Health Care Financing Administration Rulings

On Medicare, Medicaid, Professional Standards Review and Related Matters

U.S. Department of Health and Human Services
Health Care Financing Administration
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HCFA 10009 (6-80)

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Foreword

Programs of the Health Care Financing Administration—including Medicare, Medicaid, and Professional Standards Review Organizations—affect millions of people throughout the United States. To fully understand these programs, it is necessary to have access to the administrative instructions and manuals which guide staffs of Federal and State agencies and HCFA contractors in implementing the programs. In addition, official public rulings of the agency show how regulations are interpreted and applied.

Thus, in publishing *HCFA Rulings,* HCFA's intent is to observe the spirit of the Freedom of Information Act: to keep the public informed about the agency's handling of the public's business. As required by law, this document contains listings and indexes of current program regulations, manuals, instructions, rulings, and decisions. In addition, it includes recent legislation and illustrative case decisions. The case decisions serve as binding precedents upon those who administer the HCFA programs and upon those who serve as hearing officials in various program appeals. These decisions are being compiled in order to promote consistency in interpretation of policy and adjudication of disputes.

HCFA Rulings should be of use to Medicare and Medicaid beneficiaries, Federal and State employees who administer the programs, intermediaries, carriers, providers of services under the programs, other contractors to HCFA, attorneys, court and hearing personnel, and interested members of the public.

Carolyne K. Davis, Ph.D.
Administrator
Health Care Financing Administration

HCFAR 80-1 HCFAR 80-5
Publication No. HCFA 10009 (6-82)

Contents

MEDICARE PROGRAM
Hospital Insurance Benefits (Part A)

Exclusion of Heart Transplantation Procedures from Medicare Coverage

HCFAR 80-1

Purpose: This ruling establishes national policy regarding Medicare coverage of heart transplantation procedures.

Citations: Sections 1962(a)(1) and 1879 of the Social Security Act (42 U.S.C. 1395y(a)(1) and 1395pp) (45 FR 52296) (August 6, 1980).

Pertinent History: On November 2, 1979, HCFA authorized Medicare payments for heart transplantation procedures performed for Medicare beneficiaries at Stanford University Medical Center. This was an interim decision, based on preliminary findings by the Public Health Service (PHS) regarding the safety and efficacy of heart transplants performed at that center. The PHS recommendation followed a preliminary analysis of the clinical experience of heart transplantation at Stanford for a substantial number of patients. The recommendation was limited to heart transplants performed at Stanford because only that center, among all the cardiac transplant centers in the United States, had produced sufficient data about its transplant protocols and its success rates to permit an assessment of the medical safety and efficacy of its procedures.

It was our expectation, when reimbursement was tentatively authorized, that we soon would be able to reach a final decision not only about coverage at that center, but also on generally applicable, broadly based criteria for Medicare coverage of heart transplantations at all facilities where such procedures might be performed.

In the meantime, an Administrative Law Judge (ALJ) ruled that Medicare coverage should be extended to a Medicare beneficiary who received a heart transplant performed at the University of Arizona Medical Center.

As we proceeded to review Medicare coverage of heart transplants, we determined that the issues are much more complex than originally contemplated.

There are questions, for example, concerning the patient selection process, the basis for assessing safety and efficacy at medical centers other than Stanford, the long-term social and economic consequences of the procedure, broad ethical considerations, the cost effectiveness of the procedure, and the potential, if any, for substantial expansion in the availability of heart transplantation. We have concluded that there is not sufficient information to support the development of generally applicable coverage criteria.

The Medicare statute prohibits payment for any expenses incurred for items or services "which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member" (section 1862(a)(1) of the Social Security Act). In the absence of adequate data to determine whether heart transplantations meet this statutory requirement, we have determined that it is not appropriate to continue coverage of the procedure indefinitely. Therefore, we have terminated our tentative authorization to provide payment for heart transplantations.

At the same time, we have determined that the waiver of liability provisions in section 1879 of the Act (42 U.S.C. 1395pp) apply to heart transplantation procedures at Stanford and at the University of Arizona. Reimbursement of appropriate costs will continue to be provided with respect to Medicare beneficiaries who received heart transplantations, or who have been accepted as candidates for heart transplantations, at those centers on or before the effective date of this ruling.

As soon as possible, HCFA, in close cooperation with PHS National Center for Health Care Technology, will conduct a broad study of all aspects of Medicare coverage of heart transplants, including social, ethical, economic, and scientific issues. The study will also examine the impact of a coverage decision on beneficiaries, the Medicare program, and competing health care providers. The study will include patient

care costs for a limited number of Medicare beneficiaries accepted for transplantation at appropriate institutions.

When the results of the study have been analyzed, we will publish a proposed decision concerning Medicare coverage of these procedures and give the public an opportunity to participate fully in the development of the final policy, with all pertinent facts being made available for analysis.

Ruling: Effective June 13, 1980, heart transplantations and medical treatment directly associated with heart transplantation procedures are excluded from Medicare coverage, except as provided below.

Medicare payment may be made, as authorized under section 1879 of the Social Security Act, for heart transplantations and medical treatment directly associated with heart transplantations, performed on Medicare beneficiaries at Stanford University Medical Center, but only with respect to heart transplantations that (1) were performed on or before June 12, 1980, or (2) are performed on transplantation candidates accepted on or before June 12, 1980.

Exclusion from Medicare Coverage of Bilateral Carotid, Body Resection to Relieve Pulmonary Distress

HCFAR 80-2

Purpose: This ruling restates policy regarding Medicare coverage of bilateral carotid body resection to relieve pulmonary distress.

Citations: Section 1862(a)(1) of the Social Security Act (42 U.S.C. 1395y(a)(1); 42 CFR 405.310(k); 20 CFR 422.408 (45 FR 71426) (October 28, 1980).

Pertinent History: The Medicare statute prohibits payment for any expenses incurred for items or services "which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member" (section 1862(a)(1) of the Act). The Health Care Financing Administration (HCFA) has interpreted this statutory provision to exclude from Medicare coverage medical and health care services and items that are not demonstrated to be safe and effective by acceptable clinical evidence. HCFA's source of medical advice on issues of medical safety and efficacy of services and items is the Public Health Service (PHS), National Center for Health Care Technology.

Bilateral carotid body resection is sometimes performed to relieve the symptoms of pulmonary conditions such as asthma and emphysema. While this is not a common surgical procedure, a number of claims have been submitted for Medicare reimbursement. Because of questions about its efficacy and safety, HCFA requested PHS review of the procedure for purposes of Medicare coverage.

PHS has consistently advised HCFA that the bilateral carotid body resection procedure, performed to relieve the symptoms of pulmonary conditions such as asthma and emphysema, lacks general acceptance by the professional medical community because of questions concerning efficacy and safety. A thorough review of these questions was conducted in 1978 by a panel of physician specialists convened by the National Heart, Lung and Blood Institute of the National Institutes of Health (NIH). The panel reviewed all published articles on bilateral carotid body resection and obtained comments and opinions from

physicians, including surgeons, who were knowledgeable and experienced in the use of this surgical procedure as a treatment for pulmonary distress. In a report (Report of Task Force on Bilateral Carotid Body Resection, dated March 10, 1978) (see Page 7 Appendix I), the NIH panel reaffirmed earlier PHS decisions that there was not sufficient evidence to establish the safety and efficacy of the bilateral carotid body resection procedure for relief of pulmonary distress. The panel indicated its concern with the risks to the patient during the period of hospitalization for the procedure. In addition, the panel noted that "theoretical considerations suggest that the risk of hypoventilation may be increased, especially in patients with chronic obstructive pulmonary disease."

Based on this advice, HCFA issued an instruction to carriers and intermediaries in January, 1979 that Medicare does not cover carotid body resection to relieve pulmonary symptoms. (See page 25 Appendix II, Part A Intermediary Manual, Chapter II—Coverage Services Appendix, Coverage Issues.) This is the normal manner in which HCFA announces such decisions.

There have been many decisions by Departmental Administrative Law Judges (ALJs), however, that have not applied this policy and have concluded that bilateral carotid body resections were "reasonable and necessary." In 1979 the Social Security Administration's Appeals Council conducted a consolidated hearing regarding claims for bilateral carotid body resection and determined that the claims were payable under Medicare. HCFA has reviewed those proceedings, and concluded that the coverage policy on this procedure should continue to reflect the medical advice given by PHS. The purpose of this ruling, therefore, is to make our coverage decision binding on ALJs and the Appeals Council. (See 20 CFR 422.408.)

HCFA consulted with PHS when preparing this ruling, and again received advice that there is still insufficient clinical evidence to establish that bilateral carotid body resection is a safe and effective treatment for pulmonary diseases. Furthermore, there is a continued concern that the procedure is unsafe due to the risk of increased hypoventilation.

Ruling: Bilateral carotid body resection performed to relieve and treat pulmonary symptoms and diseases is not established as safe and effective and, therefore, is excluded from Medicare coverage under the authority of section 1862(a)(1) of the Act.

Effective Date: As explained above, we have previously issued policy in manual instructions excluding this service from Medicare coverage. However, since ALJs and the Appeals Council have ruled in several cases that claims for these services are payable, it is possible that some beneficiaries, relying on these rulings, have proceeded to have the operation performed in expectation of Medicare payment. In fairness to those beneficiaries, we are making the ruling effective for services furnished after the date of publication in the Federal Register, 45 FR 71426-71432, October 28, 1980.

Cross-References: *Part A Intermediary Manual,* Chapter II, Coverage of Services Appendix, Coverage Issues, §35-7; *Carriers Manual,* Chapter II, Coverage Issues Appendix, §35-7.

ATTACHMENTS

Appendix I

Report of Task Force on
Bilateral Carotid Body Resection
March 1978

Division of Lung Diseases
National Heart, Lung, and Blood Institute

U.S DEPARTMENT OF HEALTH
EDUCATION, AND WELFARE
Public Health Service
National Institutes of Health

Foreword

The Task Force on Bilateral Carotid Body Resection was constituted to advise the Division of Lung Diseases relative to a controversial issue with a long history, many ramifications and significant medical, ethical and economic implications.

In the half-century since the chemoreceptivity of the carotid body was discovered, its role in regulating ventilation under hypoxic conditions has been extensively studied in animals and man. Removal of one carotid body for symptomatic relief of intractable bronchial asthma was first performed in 1941, by K. Nakayama in Japan. In this country R.H. Overholt performed the first unilateral resection in 1961, and B. Winter the first bilateral resection in 1962. Since then thousands of patients have undergone unilateral or bilateral carotid body resection, most often for treatment of asthma, more recently for chronic bronchitis or emphysema.

There is general agreement that, in the hands of experienced surgeons, the operation *per se* is neither difficult nor dangerous; very few deaths are directly attributable to the surgery. There also appears to be general agreement that, in most cases, unilateral resection does not provide symptomatic relief for bronchial asthma. However, the biomedical community is sharply divided over the following questions:

- Does bilateral carotid body resection provide symptomatic relief for patients with bronchial asthma, chronic bronchitis or emphysema?
- Does absence of innervation of both carotid bodies place the patient at risk when confronted with situations requiring rapid ventilatory responses?
- Is it ethical to continue to use an irreversible surgical procedure when its efficacy has not been critically assessed in a controlled clinical trial?

The controversy also has economic implications. Patients undergoing bilateral resection for symptomatic relief of bronchospasm or chronic obstructive lung disease are not covered by third party payments, but probably would be if the operation were demonstrated unequivocally to be therapeutic.

The Division of Lung Diseases was drawn into this controversy when, in July 1975, Dr. Benjamin Winter wrote to the Director suggesting that a clinical trial of bilateral carotid body resection be undertaken. Stimulated by this suggestion, the Division obtained informal professional opinions from 12 well-recognized chest physicians. Their letters indicated that much of the available information was anecdotal, but little was based on firm data from controlled studies. In November 1975 a conference on *The Value of Bilateral Carotid Body Resection in Management of Patients with Severe*

*Asthma, Bronchitis or Emphysema** was held in San Francisco under the chairmanship of Dr. Julius Comroe. The report of the conference included a recommendation to "appoint a panel to prepare a protocol for a controlled, objective, prospective study of the procedure." The Pulmonary Diseases Advisory Committee reviewed the conference report and, in February 1976, recommended (1) convening a panel to develop a protocol for such a clinical trial, and (2) postponing any decision about whether to initiate a trial until a satisfactory protocol had been developed.

Because of the complexity of the issues to be addressed and the need for an indepth examination of the problem, the Division constituted a task force that was charged to:

- Review and assess the reported experimental and clinical evidence that bilateral carotid body resection is therapeutically effective in management of intractable bronchial asthma, chronic bronchitis or emphysema.
- Determine, on the basis of available evidence whether there was need for a clinical trial. If a trial was recommended,
  - — Develop a protocol that included defined endpoints and criteria for evaluating the therapeutic efficacy of the procedure.
  - — Assess the ethical problems associated with the proposed trial.

The 12-member Task Force on Bilateral Carotid Body Resection, under the chairmanship of Dr. Alan Pierce, met on May 17, and June 13, 1977, and held its final meeting on March 10, 1978. During this ten-month period, it reviewed the literature and obtained oral and written testimony from surgeons and physicians who had direct experience with patients who had undergone the procedure. Dr. Benjamin Winter and his associate Dr. Richard Baum attended the June 1977 meeting to report data on Dr. Winter's patients and, at the same meeting, Drs. Karlman Wasserman and Brian Whipp described their studies of some of Dr. Winter's patients.

Written comments were obtained from nine experts who had either performed bilateral resections or studied patients subsequent to such surgery. Dr. Y. Honda of Chiba University attended the March 1978 meeting and summarized the extensive Japanese experience, which includes 10-year and some 25-year follow-up studies of patients.

The members of the task force are listed . . . (below). Their report speaks for itself and will be presented to the Pulmonary Diseases

*Conference Participants: Drs. Cedric R. Bainton, Julius H. Comroe, Jr., Warren M. Gold, Thomas F. Hornbein, Norman Jones, Robert A. Mitchell, John F. Murray, Jay A. Nadel, John Severinghaus, Karlman Wasserman.

Advisory Committee, the National Heart, Lung, and Blood Advisory Council, and the staff of the National Heart, Lung, and Blood Institute. It will also be available for distribution to the large segments of the medical, surgical and biomedical communities interested in the issues, and to Federal and other agencies concerned with its implications for reimbursement of the costs of patient care.

In constituting the task force, the Division of Lung Diseases clearly expressed its commitment to contribute insofar as possible to resolving the controversy surrounding the use of bilateral carotid body resection for treatment of asthma, chronic bronchitis or emphysema. If the Division's Advisory Committee and the Institute's Advisory Council concur with the recommendations of the task force, the Division will take appropriate steps toward development of a protocol for a randomized, prospective clinical study that would be a definitive trial of the efficacy of bilateral resection. However, the role of the Division of Lung Diseases in implementing such a trial will depend upon approval of the Pulmonary Diseases Advisory Committee and the National Heart, Lung, and Blood Advisory Council and the availability of adequate funds.

The Report of the Task Force on Bilateral Carotid Body Resection reflects the dedication and balanced professional judgments that so many have brought to bear in arriving at the recommendations. To all those who contributed information and professional opinions to the Task Force, to the Chairman, Dr. Alan Pierce, who provided such dynamic leadership, and to all the members, whose painstaking approach, unstinting efforts and knowledgeable deliberations brought this difficult enterprise to a successful conclusion, I gratefully acknowledge their invaluable help. In expressing sincere thanks, I also speak for the Division of Lung Diseases and the National Heart, Lung, and Blood Institute.

March 10, 1978
Bethesda, Maryland

Claude Lenfant, M.D.
Director, Division of Lung Diseases
National Heart, Lung, and Blood Institute

Task Force on Bilateral Carotid Body Resection

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Report of Task Force on Bilateral Carotid Body Resection, Charge to and Rationale for Creating the Task Force

Over 400,000 deaths in the United States are attributed each year to bronchitis, emphysema, asthma, or chronic obstructive lung disease (International Classification of Disease Codes 490 to 493 and 519.3). It is estimated that there are at least 60,000 additional deaths in which these diseases are contributory causes. Approximately 35,000 Americans become totally disabled from these diseases each year, and emphysema has been second to coronary heart disease as a cause of social security-compensated disability for at least 15 years. Data from the U.S. National Health Survey indicate that chronic respiratory diseases comprise 10 percent of all conditions causing disability of one week or more. Approximately two percent of persons aged 17 years and over interviewed in the Health Interview Survey stated that they had bronchitis and/or emphysema. But this must be a minimal figure since many surveys have reported a prevalence of 10 to 40 percent depending on age, sex, and the definition of disease that are used. The economic cost of these diseases has been estimated at $5.7 billion—direct costs for hospital treatment, physicians' services, and prescribed drugs amounting to $1.0 billion and indirect costs from lost productivity due to morbidity and mortality amounting to $4.7 billion.*

It is clear, therefore, that obstructive airways diseases constitute a major health problem for the citizens of this country. Any potentially beneficial therapy for these patients must be examined by as objective criteria as possible to determine if it can play a role in decreasing this awesome morbidity or mortality. Consequently in early 1977, a Task Force on Bilateral Carotid Body Resection was appointed by the Division of Lung Diseases of the National Heart, Lung, and Blood Institute. The Task Force was charged to:

- Review and assess the reported experimental and clinical evidence that bilateral carotid body resection is therapeutically effective in management of intractable bronchial asthma, chronic bronchitis or emphysema.
- Determine, on the basis of available evidence, whether there was need for a clinical trial. If a trial was recommended,
  - — Develop a protocol that included defined endpoints and criteria for evaluating the therapeutic efficacy of the procedure.
  - — Assess the ethical problems associated with the proposed trial.

*Respiratory Diseases: Task Force Report on Preventive, Control, Education, March 1977. DHEW Publication No. (NIH) 77-1248.

Scientific Background

Anatomy of Carotid Bodies

The two carotid bodies are small structures dorsal to the bifurcations of the common carotid arteries. In humans they are located on the medial sides of these bifurcations(1). Each receives its blood supply from a branch of the carotid artery; blood flow is large relative to the mass of the tissue(2). Innervation is through the carotid sinus nerve, predominantly by glossopharyngeal afferent fibers with contributions of sympathetic efferents from the superior cervical ganglia and preganglionic parasympathetic efferent fibers from the vagus nerves(3). Utilizing the surgical technique described by Winter(1), it is possible to remove the carotid bodies without substantive damage to the lateral tracts of the carotid sinus nerves. Thus, chemoreceptor function may be ablated while preserving baroreceptor function(4).

Carotid bodies are composed of two major cell types. Type I (glomus) cells contain cytoplasmic vesicles with electron dense cores, and type II (sustentacular) cells have thin cytoplasmic extensions which ensheath the type I cells. Although the exact mechanisms are not entirely clear (2,3), it is believed that the chemoreceptor functions of the carotid bodies are mediated by the interaction of type I cells and the afferent fibers of the glossopharyngeal nerves.

Physiology of Carotid Bodies

The major physiological stimulus to the carotid bodies is a reduction in the arterial oxygen tension (PaO_2) which leads to an increase in ventilation. The carotid bodies are active at a PaO_2 that is normal while breathing ambient air at sea level. This activity is suppressed by the administration of high inspired oxygen concentrations. However, the carotid body effect at such PaO_2's is small and difficult to demonstrate. Conversely, the effects on ventilation at lower PaO_2's are more striking and are readily demonstrated by administering low inspired oxygen concentrations. The hypoxemia-induced hyperventilation is blunted by the effect of the resultant low arterial carbon dioxide tension ($PaCO_2$) acting on central chemoreceptors (4). Thus, the carotid body response to low PaO_2's may be more clearly demonstrated by maintaining a constant $PaCO_2$ by the administration of carbon dioxide in the inspired gas.

Some studies of patients who have had both carotid bodies removed (5,6) or who have had carotid endarterectomies (7) have demonstrated that the ventilatory response to acute hypoxemia is entirely lost, while others have reported that a weak response remains (8-11). The mediators of the small remaining response in some patients are not known but could represent a function of the aortic body or could represent regeneration of sensory terminals at

the site of glomectomy (12). Not only is there no, or minimal, ventilatory response to severe hypoxemia in patients following bilateral carotid body removal, but there may also be no discomfort or dyspnea when they are subjected to severe hypoxemia. An objective assessment of this latter phenomenon may be the observation that patients without carotid bodies can hold their breaths considerably longer than normal persons when each is subjected to hypoxemia (11,13).

The carotid bodies are also stimulated by a decrease in arterial pH (14). The minimal stimulatory effect of increasing $PaCO_2$ is thought to be mainly through its influence on pH (15). Stimulation of ventilation by $PaCO_2$ is predominantly through central nervous system chemoreceptors. Carotid body chemoreceptors are also responsible for the increased ventilation which accompanies the metabolic acidosis of heavy exercise, and may contribute to ventilatory drive at the outset of exercise (16). Although normal long-term residents of high altitude have an attenuated ventilatory response to acute hypoxemia (17,18), they apparently have normal responsiveness of their carotid bodies during exercise (18). Such is not the case for patients who have had bilateral carotid body resections (5).

The carotid bodies are sensitive to other stimuli, such as a change in blood temperature and a decrease in blood flow to the chemoreceptor cells, and they initiate a variety of responses in addition to increasing ventilation (19). The most important additional reflex for the purpose of the Task Force is the finding of Nadel and Widdicombe that stimuli to the carotid body, such as hypoxemia, cause an increase in airway resistance in dogs (20). It was further demonstrated that the glossopharyngeal nerves are the afferent limbs of this reflex, and the vagi are the efferent limbs. This work has been cited (1,21) as the rationale for the symptomatic improvement reported by some patients with airways obstructive disease following bilateral carotid body resection. However, the results of various studies in regard to this reflex in humans are conflicting. Butler *et al.* found no effect of breathing pure oxygen (22), but Saunders *et al* found that hypoxia decreased airway conductance (23). Schiffman *et al* found that oxygen caused attenuation of exercise-induced bronchospasm (24) and Astin and Penman presented data suggesting that breathing 30 percent oxygen decreased airway resistance in patients with chronic obstructive airway disease (25). Thus, the members of the Task Force are not aware of a definitive demonstration of this reflex in normal humans or patients with airways obstructive disease.

Unilateral Carotid Body Resection

Although unilateral carotid body resections for patients with airways obstructive disease had been practiced in Japan since the 1940's, the first reports in the literature of this country were in 1961

(26,27). Since that time the results of this procedure have been reported both in a large number of patients purported to have asthma and in patients with chronic bronchitis and emphysema (28-40). These reports conflict concerning the clinical benefits of unilateral carotid body resection. In these studies neither sham-operated nor unoperated control patients were studied; patients were usually not well characterized as to type of airways disease; pulmonary function studies pre- and post-operatively were usually not reported; and the usual assessment was only the subjective impression of the patients and the surgeons who had performed the operation. Thus, the Task Force views with skepticism those reports suggesting a clinical improvement in a high fraction of patients, and questions whether the reported results were due to a change in pathophysiological mechanisms or to psychological factors.

Three double-blinded or controlled studies of unilateral carotid body resections have been reported (41-44). These studies have provided convincing evidence that unilateral resection of a carotid body is of no value in the treatment of airways obstructive disease. Thus, the Task Force agrees with the Committee on Therapy of the American Thoracic Society that "this procedure has no place in the treatment of patients with asthma or emphysema" (45).

Bilateral Carotid Body Resection

The clinical results of patients who have had bilateral carotid body resections for airways obstructive disease have not been as frequently reported (1,21,26,28-30,33,37,46-49), and these patients are not separately reported from unilaterally operated patients in some series. Nevertheless a sufficient number of patients have been operated to have definitively determined the efficacy of this procedure had the patients been studied and reported more completely. Unfortunately, in the judgment of the Task Force, the published reports of patients who have undergone bilateral carotid body resection do not allow the conclusion that the procedure is beneficial to patients with airways obstructive disease. This decision has been reached because of a lack of sufficient information concerning:

1. sham-operated control patients; or
2. similar patients randomized to operated and non-operated groups;
3. characterization of the type of airways disease and its therapy in operated patients;
4. assessment of pulmonary functions pre- and post-operatively;
5. characterization of results of surgery and long-term follow-up of operated patients; and
6. the potential detrimental effects of such surgery.

Conversely, this same lack of information prevents the definite conclusion that bilateral carotid body resection does not clinically benefit patients with airways obstructive diseases. In addition to a potential decrease in airway resistance by the reflexes demonstrated in dogs, it could be that an absence of a hypoxemic ventilatory drive might decrease dyspnea and result in greator comfort in selected patients (50). The frequency with which a loss of hypoxemic drive during episodes of acute hypoxemia from any cause would lead to potentially fatal events or to more rapidly progressive pulmonary insufficiency also cannot be estimated, and hence the net result to the patient's overall well being cannot be accurately predicted.

Conclusions

The Task Force has carried out an extensive review of published material and solicited comments, both oral and written, from surgeons who perform bilateral carotid resection and from physicians who follow these patients.

The Task Force is unanimous in its view that before any procedure can be recommended as a therapeutic measure there should be a clear demonstration of efficacy and documentation that risk is acceptably small. The panel believes that in the case of bilateral carotid body resection neither criterion is met. Specifically, the benefits of bilateral carotid body resection have not been clearly shown. Even in the hands of experienced surgeons the procedure has a significant in-hospital mortality rate, and theoretical considerations suggest that the risk of hypoventilation may be increased, especially in patients with chronic obstructive pulmonary disease. This latter group appears to constitute a major source of candidates for this operation as recent progress in the pharmacological treatment of asthma has markedly reduced the number of asthmatic patients in whom glomectomy would be considered. Thus the patient with chronic obstructive pulmonary disease who is unresponsive to medical therapy is most likely to become a candidate for this operation.

While it has been concluded that bilateral carotid body resection cannot presently be recommended because of currently inadequate demonstrations of benefits and of risks, a clear documentation of the utility of bilateral carotid body resection and its risks could arise from a carefully designed study of patients currently undergoing carotid body resection.

Rationale for Recommendations

Having concluded that there is no incontrovertible evidence to support the use of bilateral carotid body resection as a therapeutic procedure and that the data do not refute the potential that the procedure is harmful, the Task Force recommends that a carefully designed clinical study be undertaken. This trial should be limited to

patients with chronic bronchitis and emphysema (COLD). Recent advances such as inhaled steroid preparations, selective -agonist agents, and cromolyn sodium have made the management of most patients with reversible alrways disease, asthma, more satisfactory than in former times. The Task Force does not believe that the permanent ablation of a ventilatory response to hypoxemia can be justified in these generally younger age range patients at the present. The Task Force further recommends that no patient be recruited into such a study who would not otherwise have undergone bilateral carotid body resection.

The best study design would compare patients in whom carotid body resection had been carried out with control subjects in whom a sham operation had been performed. The two groups would be selected at random, assessed pre- and postoperatively and followed concurrently by independent observers who are unaware of the patient's operative status. The Task Force does not believe that, despite the greater scientific validity, sham operations are ethical. A prospective clinical trial of patients with COLD, who desire bilateral carotid body resection and who have been deemed suitable for this procedure by participating surgeon(s) is therefore recommended. Such subjects will be randomized into a group that receives immediate operation and a group in which this operation is delayed for one year. Initial assessment, randomization and follow-up of both cases and controls and analysis of the resulting data will be performed by physicians and scientists who do not themselves perform the operation. Emphasis will be placed on objective methods of evaluation (lung function tests, activity capacity, expectation of life, etc.), though subjective assessment will clearly also be involved (symptoms, medications, feelings and mood). Every effort will be made to incorporate blind assessment of the observers into these subjective evaluations.

Initial assessment should include extensive historical and physiological information to insure that a baseline for future comparisons is secure. The physiological data must be sufficiently extensive to not only determine the extent of pulmonary and cardiac derangement but also to define the type of pulmonary disease insofar as possible. Estimates of exercise capacity and hypoxemia during sleep should be determined. Following randomization and operation of some patients, all patients should have periodic reassessment which includes all of the initial studies on a recurring basis for at least two years. Additionally, patients should keep standardized diaries of symptoms, medications, activity, and feelings and moods.

Short-term physiological studies to assess ventilatory responses should be performed initially and recurrently in operated patients and controls. Such studies will not only confirm the loss of carotid body chemoreceptors in operated patients but will also help establish a basis for improvement if such occurs or of detrimental effects if such occur.

Recommendations

1. A clinical trial to determine the potential benefits and detrimental effects of bilateral carotid body resection should be undertaken. The operation should be performed by a surgical technique which does not interfere with carotid sinus baroreceptors.
2. Potential candidates for the trial are men and women judged to have chronic obstructive lung disease between the ages of 45 and 74 years. Patients with reversible airways disease, asthma, should be excluded. Exclusion for asthma should be based on the patient's history and/or reversibility of airways obstruction demonstrated by spirometry before and after bronchodilators. Patients with other serious medical diseases such as carcinoma or diabetes should also be excluded.
3. Patients with COLD should not be specifically recruited for the trial of this surgical procedure. Candidates for this trial are patients who have applied to a surgeon to have the operation performed.
4. Patients who have sought surgical intervention should be sent by the cooperating surgeon(s) to a specified neutral observer(s) who will select the potential study patients based on the criteria in recommendation 2. These patients should be fully informed about the potential benefits and risks of bilateral carotid body resection and about the requirements, benefits, and risks of the study. Informed consent must be obtained before entering the trial.
5. Patients entering the trial should be randomly assigned by the neutral observer(s) into a group who will receive bilateral carotid body resection and a control group who will not for at least one year.
6. A two-stage study should be undertaken. In Stage 1 approximately 60 patients should be equally randomized into operated and control groups. When these patients have each been followed for at least one year, all data should be analyzed for statistical differences between the groups. If the observed differences are too small or the variability is too large such that additional observations would not be useful, the trial should be terminated. If the data reveal trends of interest that are not statistically significant, a Stage 2 with the study of additional patients should be undertaken.
7. The initial assessment of each study patient by a neutral observer(s) should include the following:
   a. A standardized history such as the modified British Medical Research Council questionnaire and a complete physical examination.

b. Pulmonary functional assessment including spirometry before and after bronchodilators with calculation of FVC, FEV1, FEF25-75%; lung volumes; diffusing capacity; and arterial blood gases while breathing room air.

c. Cardiac assessment including ECG and chest radiograph for heart size.

d. The blood gas, ventilation, and heart rate response to standardized exercise testing.

e. The respiratory pattern, arterial oxygenation as measured by ear oximetry, and cardiac rhythm during normal sleep.

f. The ventilatory responses outlined in recommendation 10.

g. Psychological and neuropsychological studies such as the Wechsler Adult Intelligence Scale; Wechsler Bellevue Intelligence Scale; Full Scale, Performance, and Verbal IQ's; Wechsler Memory Scale; Bender-Gestalt; Background Interference Procedure; Finger Tapping; and Facial Recognition Test.

8. At the time of the original assessment, the neutral observer(s) should instruct each patient on the maintenance of a standardized diary which includes activities, medications, symptoms, physician visits, hospitalizations, appetite, weight, sleep, and the patient's mood (on a 4-point scale).

9. The neutral observer(s) will repeat the testing indicated in recommendation 7 on the 3rd or 4th postoperative day and at 1, 3, 6, 12, 18, and 24 months. Control patients will have a day assigned that will correspond to the day of operation, and tests will be repeated accordingly. At each test interval the neutral observer(s) will validate and collect the standardized interval diary.

10. Short-term physiological studies to establish a basis for improvement or detrimental effects of bilateral carotid body resection should be performed. These studies should be directed at a potential bronchoconstrictor reflex in humans mediated by the carotid bodies and at the importance of carotid bodies in regulation of respiration.

    Studies should be performed to establish whether hypoxemia narrows and hyperoxia dilates the airways of humans. The COLD patients of this trial should be compared in this regard to asthmatic patients and to normal subjects. If hypoxemia constricts the airways, studies should be designed to establish whether the carotid body is involved in the effect. Anticholinergic drugs can be used to study the role of post-ganglionic cholinergic pathways in the response.

    For regulation of respiration studies, it is realized that the patients will have such severe pulmonary disease that rigorous

determination of the responses to carbon dioxide and hypoxemia should not be expected. However, efforts should be directed toward defining the resting level of blood gases, the set point of PCO2, and the magnitude of response to carbon dioxide and hypoxemia before and after surgery. In addition, a recording of the ventilatory response to a standardized dose of Doxapram should be carried out. The recommended tests to be done on all patients include:

a. Resting blood gas determinations.

b. Repeat blood gases after 10 minutes of breathing 100% oxygen.

c. Doxapram response.

d. Response to elevated CO2 at high oxygen with at least one steady state point to establish a set point of CO2.

e. Ventilatory response to reduction of alveolar O2 at constant, somewhat elevated CO2 while monitoring some index of arterial oxygenation such as ear oximetry, transcutaneous PO2 electrode, or in-dwelling arterial PO2 or saturation indicator.

An extensive analysis and discussion of these tests has been published recently (51).

In addition, the Doxapram test would be helpful intraoperatively before and after carotid body resection under anesthesia. This test would help establish that the removal of carotid body chemoreceptors was complete.

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Appendix II

Part A Intermediary Manual

Chapter II—Coverage of Services

Coverage Issues

The material in this appendix represents responses to questions about coverage of services under Medicare.

These responses are based on existing resource material and where there are medical implications on advice received from both Government and non-government sources, including opinions from appropriate specialists in the medical community.

35-7 Carotid Body Resection/Carotid Body Denervation

Carotid body resection is occasionally used to relieve pulmonary symptoms, including asthma, but has been shown to lack general acceptance of the professional medical community. In addition, controlled clinical studies establishing the safety and effectiveness of this procedure are needed. Therefore, all carotid body resections to relieve pulmonary symptoms must be considered investigational and cannot be considered reasonable and necessary within the meaning of section 1862(a)(1) of the law. No program reimbursement may be made in such cases.

There is, however, one instance where carotid body resection has been accepted by the medical community as effective. That instance is when evidence of a mass in the carotid body, *with or without symptoms,* indicates the need for surgery to remove the carotid body tumor.

Denervation of a carotid sinus to treat hypersensitive carotid sinus reflex is another procedure performed in the area of the carotid body. In the case of hypersensitive carotid sinus, light pressure on the upper part of the neck (such as might be experienced when turning or raising one's head) results in symptoms such as dizziness or syncope due to hypotension and slowed heart rate. Failure of medical therapy and continued deterioration in the condition of the patient in such cases may indicate need for surgery. Denervation of the carotid sinus is rarely performed, but when elected as the therapy of choice with the above indications, this procedure may be considered reasonable and necessary.

Miscellaneous Provisions (Part C)

Sections 1866 and 1870 (42 U.S.C. 1395cc and 1395gg)—Provider Reimbursement—Statute of Limitations on Recovery of Overpayments—Failure to File Cost Reports—Expert Witnesses

HCFAR 80-3

U.S. v. Joseph R. McCarthy d/b/a Health Care at Home (C.D. CA, No. CV 76-0315-DWW)

A Medicare provider was overpaid $154,838 in Medicare reimbursement, some of which was due to the provider's failure to file a cost report. When the provider failed to pay the debt, HCFA brought suit seeking recovery of the overpayment plus interest from the date of demand.

Held, 1) The statute of limitations begins to run, in a Medicare overpayment case in which a cost report has been filed, when the fiscal intermediary completes its review and notifies the provider of the auditor's report.

2) The provider's failure to file a cost report gives rise to a conclusive presumption that all interim payments received for the period were an overpayment.

3) A HCFA regional office accountant may qualify as an expert in Medicare accounting and is competent to testify as to the propriety of the audit adjustments made by the intermediary, despite the fact that the accountant did not personally make the adjustments.

4) The Federal government is entitled to prejudgment interest from the date of first demand.

WILLIAMS, DISTRICT JUDGE:

The court having fully considered the evidence and arguments of counsel, and being fully advised, makes the following Findings of Fact and Conclusions of Law:

Findings of Fact

1. This is an action brought by plaintiff United States of America to recover overpayments made to defendant Joseph R. McCarthy while he participated as a provider of services under the Medicare Act, 42 U.S.C. 1395 *et seq.*

2. Plaintiff filed its complaint on January 28, 1976. Defendant filed an answer and amended counterclaim which sought a setoff against plaintiff's claim.

3. Defendant Joseph R. McCarthy, doing business as Health Care at Home, participated in the Medicare Program as provider of services from September 6, 1967 to February 1, 1971.

4. During said time of participation Health Care at Home was a home health agency which provided physical therapy and other

services under Part A and Part B of the Medicare Program to Medicare beneficiaries in their homes.

5. During said time of participation, interim payments were periodically made to the defendant under the program for covered services furnished to Medicare beneficiaries.

6. In accordance with 20 C.F.R. 405.401 *et seq.*[1] and 42 U.S.C. 1395 *et seq.*, defendant was required to file cost reports to substantiate his claim for reimbursement for services rendered to beneficiaries under the program.

7. In respect to defendant's cost period ending June 30, 1968, defendant filed a cost report on February 17, 1969, and an amended cost report on June 27, 1969. The Secretary of Health, Education and Welfare, acting through his fiscal intermediary Blue Cross of Southern California, requested John F. Forbes and Co. to perform an audit on defendant's cost report. John F. Forbes and Co. submitted its report to Blue Cross of Southern California, and on July 15, 1970, Blue Cross completed its review of John F. Forbes' report. On that date the audit of defendant's cost report was complete, a final reimbursement determination was made, and official notice of that determination was sent to defendant.

8. In respect to defendant's cost period ending June 30, 1969, defendant submitted a cost report on January 2, 1970. The Secretary of Health, Education and Welfare, acting through his fiscal intermediary Blue Cross of Southern California, undertook a review of this cost report. This review was complete on February 15, 1972.

9. At trial plaintiff called Mr. Thomas Coupar, an employee of the Medicare Bureau, Health Care Financing Administration, U.S. Department of Health, Education and Welfare, to testify. Mr. Coupar described the adjustments including those prepared by contract auditors made by the fiscal intermediary to the cost reports, and testified that these adjustments were made in accordance with Medicare regulations.

10. The audit adjustments made to defendant's cost reports for the periods ending June 30, 1968 and June 30, 1969 were proper and in accordance with statute and regulations.

11. In respect to the defendant's cost period ending June 30, 1968, the cost report as audited indicated that defendant was overpaid by $29,255.00. This amount is still owing to plaintiff.

12. In respect to defendant's cost period ending June 30, 1969, the cost report as audited indicated that defendant was overpaid by $209,664.00 and this amount is still owing to plaintiff.

13. In respect to defendant's cost period ending June 30, 1970, defendant filed a cost report which after audit showed that defendant was underpaid by $134,769.00. Additionally defendant submitted claims to plaintiff for payment in respect to which Blue Cross determined $49,606.00 was due. Plaintiff has withheld payment of the

1. Now recodified at 42 CFR 405.401 et seq.

underpayment and claims, and in lieu thereof has offset the monies against the amount due to plaintiff.

14. Defendant did not submit a cost report for the cost period from July 1, 1970 through February 1, 1971. During this period defendant had received $4,863.00 in interim payments.

15. During the period in which defendant participated in the Medicare program, defendant received current financing payments which were, in effect, non-interest bearing loans made to improve defendant's cash flow. Defendant received $95,431.00 in current financing payments which have not been repaid.

16. As a result of the foregoing overpayments, underpayments, claim withholds, failure to file a cost report, and failure to repayment current financing, defendant is indebted to plaintiff in the amount of $154,838.00, plus interest at the rate of 7% per annum from the date of first demand: $20,264.65 in interest on that portion of the overpayment arising from the cost reporting period ending June 30, 1968, for which demand was made on July 15, 1970; $44,074.32 in interest on the amount due from the cost reporting periods ending June 30, 1969 and June 30, 1970 for which demand was made on February 15, 1972; and $28,271.62 in interest on the remainder for which demand was made on April 26, 1972; for a total amount of $247,448.59.

17. To the extent these Findings of Fact contain Conclusions of Law, they shall be deemed to be incorporated within the Conclusions of Law.

Conclusions of Law

1. This court has jurisdiction of this action pursuant to 28 U.S.C. 2456.

2. This court has jurisdiction over the parties.

3. In respect to the fiscal year ending June 30, 1968, plaintiff's cause of action did not accrue until its fiscal intermediary completed its review of the auditor's report. This occurred on July 15, 1970. Because plaintiff's complaint was filed less than six years after this date, plaintiff's claim to recover any overpayments arising for the cost period ending June 30, 1968 is not barred by the applicable statute of limitations. *United States* v.*Withrow,* 593 F.2d 802 (7th Cir. 1979).

4. In respect to the cost period ending June 30, 1969, plaintiff's cause of action accrued upon the fiscal intermediary's completion of its review of defendant's cost report. This event occurred on February 15, 1972. Because plaintiff's complaint was filed less than six years after this date, plaintiff's claim to recover any overpayment arising from this period is not barred by the applicable statute of limitations. *United States* v. *Withrow, supra.*

5. In respect to defendant's fiscal period ending February 1, 1971, no cost report was filed by defendant. Plaintiff's claim for any

overpayment arising from this period is not barred by the applicable statute of limitations.

6. Plaintiff's claim to recover the current financing payments received by defendant is not barred by the applicable statute of limitations.

7. Mr. Thomas Coupar, as an expert on Medicare accounting, was competent to testify as to the propriety of the adjustments made by the fiscal intermediary to the cost report, notwithstanding the fact that he personally did not make those adjustments.

8. The adjustments made by the fiscal intermediary to cost reports ending June 30, 1968 and 1969 were proper and in accordance with statute and regulation.

9. The failure to file a cost report for the period ending February 1, 1971, gave rise to a conclusive presumption that all interim payments received for that period were an overpayment. *United States* v. *Upper Valley Clinic Hospital,* 615 F.2d 302 (5th Cir., April 10, 1980).

10. Plaintiff is entitled to pre-judgment interest at the legal rate in the State of California of 7% per annum from the date of first demand for the amount owing.

11. Judgment shall be entered for plaintiff and against defendant in the sum of $154,838.00 principal, $92,610.59 prejudgment interest, for a total sum of $247,448.59, plus costs. Judgment shall be entered in favor of counter-defendant and against counter-plaintiff, and defendant shall take nothing, on defendant's amended counterclaim.

12. To the extent these Conclusions of Law contain Findings of Fact, they shall be deemed to be incorporated within the Findings of Fact.

Sections 1861(v)(1), 1866, and 1978 (42 U.S.C. 1395x(v)(1), 1395cc, and 1395oo)—Provider Reimbursement—Related Organizations—Inclusion in Allowable Costs of Payments Made Pursuant to Lease and Management Agreements

42 CFR 405.419, 405.427, 405.1829, and 405.1867 HCFAR 80-4

Medical Center of Independence v. Harris, Medicare and Medicaid Guide, (CCH) ¶ 30,654 (8th Cir. 1980)

A provider sought reimbursement for rent, management service fees, and interest expense paid to a management company. The hospital management company had acquired the assets of a partially constructed hospital. The construction project was already in financial trouble. The management company entered into a long-term agreement to lease the facility to a corporation formed to operate the facility, to manage it for the provider, and to loan the provider up to $200,000, if needed. The management company thereafter had 43 percent representation on the provider's board of directors, had two of its employees serve as officers of the provider, and the provider's administrator became a management company employee. Only the management company had the right to cancel the lease; and, if canceled, it was

to assume the assets and liabilities of the provider. Prior to their agreement, there was no relationship between the management company and the provider.

42 CFR 405.427 states that costs for services, facilities, and supplies furnished to a provider by an organization related to the provider by common ownership or control are to be reimbursed at the cost to the related organization, rather than at the cost to the provider. Similarly, 42 CFR 405.419(c) disallows interest expense paid to related organizations.

Held, applicability of the related organization rule which limits costs of a provider to those of its supplier is not necessarily determined by the absence of a relationship between the parties prior to their initial contracting, although this fact is to be considered. The applicability of the rule is determined by also considering the relationship between the parties according to the rights created by their contract. The terms of the contracts and events which occurred subsequent to the execution of the contracts in this case had the effect of placing the provider under the control of the supplier.

Further held, the management company is related to the provider by control because the management company had the power, directly or indirectly, to significantly influence or direct the actions or policies of the provider, and therefore reimbursement for rent and management services to the provider is charged at the cost to the management rather than at the cost to the provider. Also, interest expense is not recoverable.

Further held, because the Secretary has established by substantial evidence the applicability of the related organization rule to the facts in this case, the Secretary does not need to determine the unreasonableness of particular costs.

Further held, the question of whether a related organization actually exercised the power to control is immaterial to the issue of whether control exists.*

BRIGHT, CIRCUIT JUDGE:

Medical Center of Independence, Inc. (MCI), appeals from a judgment of the district court[1] denying MCI reimbursement under the Medicare program for certain management fees, interest expense, and rent. On appeal, MCI argues that the district court erred in its interpretation and application of the "related organization principle" found in 42 C.F.R. 405.427 (1979). We disagree and therefore affirm.

I. Background

MCI leases and operates a hospital facility in Independence, Missouri, with a financially troubled history. The Lutheran Missionary Homestead Association, Inc. (LMHA), begun construction on the hospital in 1966. LMHA was unable to sell enough bonds to complete construction, and soon it was forced into Chapter X bankruptcy proceedings. Pursuant to a court-approved 1968 plan of reorganization, MCI was formed as a nonprofit corporation to

*In upholding the decision of the district court, the appellate court did not dispute this finding of the district court.

[1]The Honorable Elmo B. Hunter, United States District Judge for the Western District of Missouri. The district court opinion is reported in *Medicare & Medicaid Guide* (CCH) ¶ 29,948 (1979).

operate the hospital when completed. Americare Center, Inc., a hospital management firm, acquired all the assets of LMHA in return for satisfying certain creditor's claims and undertaking to complete the hospital facility and lease it to MCI. MCI agreed to operate the facility as a general acute care hospital, to engage Americare as a management company, and to give notes to various creditors.

Americare completed construction of the hospital but began to fail financially and had difficulty equipping the facility. MCI advertised in health care journals in an effort to locate a successor management contractor to Americare. Having received no satisfactory response to its advertisements, MCI entered into negotiations with Hospital Affiliates International, Inc. (HAI). On June 19, 1970, HAI purchased the assets of the hospital from Americare. HAI then entered into a fifteen-year lease with MCI, to become effective August 1, 1970, and a management agreement to run concurrently with the lease. HAI also agreed, as had Americare, to lend up to $200,000 in necessary working capital to MCI.

In August 1970, the bylaws of the hospital were amended to increase the number of directors from eleven to fourteen, to allow nonlocal directors to vote by proxy, and to increase the number of officers' positions. In October 1970, six HAI employees were elected as directors of MCI; two were also elected as MCI officers. Under HAI's direction the hospital began operation and soon became a successful enterprise.

Since the hospital opened MCI has served as a provider of health services under Medicare Part A, 42 U.S.C. 1395c-1395 (1976 & Supp. II 1978). *See* 42 U.S.C. 1395x(u)(1976). As such, MCI does not bill patients who are eligible under Medicare for covered services. *See* 42 U.S.C. 1395cc (1976 & Supp. II 1978). Instead, it is to be reimbursed by the Government for its reasonable cost of providing these services or, if lower, the customary charges for them. *See* 42 U.S.C. 1395(f)(b)(1976 & Supp. II 1978).

A provider may be reimbursed for services rendered to Medicare beneficiaries either directly by the Secretary of Health and Human Services (the Secretary)[2] or through a "fiscal intermediary" that acts as the Secretary's agent for purposes of reviewing claims and administering governmental payments. *See generally Blue Cross Association v. Harris,* Nos. 79-1732, 79-1733 (8th Cir. June 6, 1980); *Columbus Community Hospital, Inc. v. Califano*, 614 F.2d 181, 183 (8th Cir. 1980). If a provider is dissatisfied with the fiscal intermediary's determination regarding its claim for costs, it may request a hearing on the matter before the Provider Reimbursement Review Board (PRRB). 42 U.S.C. 1395oo(a)(1976). The PRRB's determination is the final agency action unless the Secretary, on her own motion and within sixty days after the provider of services is notified of the PRRB's decision, reverses or modifies that decision. 42 U.S.C. 1395oo(f)(1)(1976).

[2]The Secretary was formerly known as Secretary of Health, Education and Welfare.

Although reimbursement under the Medicare program is structured around the concept of reasonable costs, the Medicare statute sets forth only a broad guideline for determining such costs:

> The reasonable cost of any services shall be the cost actually incurred, excluding therefrom any part of incurred cost found to be unnecessary in the efficient delivery of needed health services, and shall be determined in accordance with regulations establishing the method or methods to be used, and the items to be included, in determining such costs[.] [42 U.S.C. 1395x (v)(1)(A)(1976).]

The statute requires that the Secretary's regulations take into account the direct and indirect costs necessary for the efficient delivery of covered services to Medicare beneficiaries, so that these costs will not be borne by noncovered idividuals. 42 U.S.C. 1395x(v)(1)(A)(i)(1976).

The Secretary's regulations governing reimbursement of Medicare providers are codified at 42 C.F.R. 405.401-405.488 (1979). As a general rule, payments made by a provider to an outside party for interest expense, facilities, and services are eligible for reimbursement at the provider's cost so long as the payments are reasonable and related to patient care. Under 42 C.F.R. 405.427 (1979), however, if the provider and its supplier are "related organizations," reimbursement will be limited to the supplier's cost. 42 C.F.R. 405.427 (1979) provides in relevant part as follows:

> (a) *Principle.* Costs applicable to services, facilities, and supplies furnished to the provider by organizations related to the provider by common ownership or control are includable in the allowable cost of the provider at the cost to the related organization. However, such costs must not exceed the price of comparable services, facilities, or supplies that could be purchased elsewhere.
>
> (b) *Definitions*—(1) *Related to provider.* Related to the provider means that the provider to a significant extent is associated or affiliated with or has control of or is controlled by the organization furnishing the services, facilities, or supplies.
>
> (2) *Common ownership.* Common ownership exists when an individual or individuals possess significant ownership or equity in the provider and the institution or organization serving the provider.
>
> (3) *Control.* Control exists where an individual or an organization has the power, directly or indirectly, significantly to influence or direct the actions or policies of an organization or institution.

When MCI's fiscal intermediary, Blue Cross of Kansas City, audited MCI's cost reports for fiscal years 1970-73, it determined that MCI and HAI were related through common control. In accordance with the terms of 42 C.F.R. 405.427 (1979), the intermediary disallowed part of the interest expense, management fees, and rental payments claimed by MCI, reducing its Medicare reimbursement for those

years by over $300,000. Only the reimbursement for fiscal year 1973 is before us in this case.[3]

MCI appealed the intermediary's 1973 determination to the PRRB. The PRRB rendered a decision in MCI's favor, concluding that MCI had introduced substantial evidence that it and HAI were not related at the time that they entered into their agreement, and that HAI exercised no significant control over MCI thereafter. Subsequently, the Commissioner of Social Security (the Commissioner), acting pursuant to authority delegated by the Secretary, reversed the PRRB's decision. The Commissioner held that the PRRB erred in interpreting 42 C.F.R. 405.427 (1979) to require the actual exercise of control by one organization over another; according to the Commissioner, HAI's power to control MCI was sufficient to make them related organizations within the meaning of the regulation.

MCI appealed this determination to the district court pursuant to 42 U.S.C. 1395oo(f)(1)(1976). MCI argued before the district court (1) that the Commissioner was an improper delegate of the Secretary's authority; (2) that the Commissioner's decision was erroneous because it was not supported by substantial evidence; and (3) that the Commissioner's decision was erroneous because the related party principle does not apply to contracts between organizations that are unrelated at the time of contracting. The district court rejected all three contentions. On appeal, MCI renews its challenge to the correctness of the Commissioner's decision under 42 C.F.R. 405.427 (1975), and in addition challenges the validity of the regulation as applied in this case.

II. Analysis

A. Standard of Review

B. Sufficiency of the Evidence

The district court, having thoroughly reviewed the record in this case, concluded that substantial evidence supported the Commissioner's finding that HAI had "the power, directly or indirectly, significantly to influence or direct the actions or policies of [MCI]." 42 C.F.R. 405.427(b)(3)(1979). The court noted that HAI had six representatives on MCI's fourteen-member board of directors; that two HAI officials were elected to serve as vice president and assistant

[3]Because the PRRB has jurisdiction to hear appeals only for reporting periods ending June 30, 1973, or after, MCI pursued its appeals for fiscal years 1970, 1971, and 1972 through Blue Cross Association. These appeals proved fruitless, and MCI sought judicial review in the district court. On July 13, 1977, the district court dismissed without prejudice MCI's claims for fiscal years 1970-72 because the court lacked federal jurisdiction and MCI had failed to exhaust its administrative remedies. *Medical Center of Independence v. Califano,* 433 F. Supp. 837 (W.D. Mo. 1977). MCI has since filed a petition in the United States Court of Claims seeking review of adverse administrative determinations for those years.

secretary of MCI in October 1970; and that MCI's administrator became an employee of HAI in 1972. The court also noted that only HAI could cancel the lease agreement between itself and MCI, and if it were cancelled, HAI would assume all of MCI's assets and liabilities.

We agree with the district court that substantial evidence in the record demonstrates HAI's power to control MCI. *Cf. Fallston General Hospital v. Harris,* 481 F. Supp. 1066 (d. Md. 1979) (control test satisfied where general partner in a limited partnership hospital was empowered to enter into and perform a lease agreement with a lessor owned by the general partner); *Fairfax Hospital Ass'n, Inc. v. Mathews*, 459 F. Supp. 429, 433-36 (E.D. Va. 1977), *aff'd sub nom. Fairfax Hospital Ass'n, Inc. v. Califano*, 585 F.2d 602 (4th Cir. 1978) (pharmacist and hospital related by his power of control where he had helped organize hospital, had obtained pharmacy leased on favorable terms, and had served as an officer and director); *Hillside Community Hospital of Ukiah v. Mathews,* 423 F. Supp. 1168, 1173-75 (N.D. Cal. 1976) (seller of land and hospital building had power of control where three members of the board of directors of the hospital together owned 46.5% of the seller).

MCI on this appeal does not directly attack the substantiality of the evidence supporting the Commissioner's determination; rather, it argues that the Commissioner erred in overlooking or discounting several instances in which HAI failed to control MCI's actions. This error, MCI contends, is due to the Commissioner's equation of potential influences with actual influence or control. We note, however, that this equation is implicit in the language of 42 C.F.R. 405.427 (1979), which focuses on the *power* to control. Power is not necessarily lost, and may in fact be enhanced, by its infrequent exercise. *Cf. Fallston General Hospital v. Harris, supra,* 481 F. Supp. at 1069 (power to direct actions of provider not lost by its delegation to management company).

MCI also argues that the Commissioner erred in glossing over the question of the significance of HAI's control. In part this argument simply restates MCI's contention that potential influence is insufficient to warrant a finding of control. More importantly, MCI claims that the requirement of significant influence precludes the Commissioner from using evidence of influence gained at the time of contracting to establish control over the terms of the contract. Both challenges raise the question of whether the regulation, as interpreted and applied in this case, comports with the language and intent of the Medicare statute. To this question we now turn.

C. The Commissioner's Decision and Statutory Requirements

The Medicare Act requires reimbursement of all costs incurred by providers in serving beneficiaries, except (1) costs not actually incurred, (2) unnecessary costs, (3) costs attributable to noncovered services, and (4) costs that are unreasonable in amount 42 U.S.C.

1395f and 1395x(v)(1)(A)(1976 & Supp. II 1978). The related organization principle embodied in 42 C.F.R. 405.427 (1979) serves to screen out both costs not actually incurred and unreasonable costs. That is to say, the regulation precludes reimbursement for cost increases due solely to transactions between different parts of a single economic unit,[5] and it polices "sweetheart" contracts with suppliers that may inflate costs to the provider.[6]

MCI does not take issue with these goals. Nor does it challenge 42 C.F.R 405.427 (1979) as drafted.[7] MCI argues rather that the Commissioner failed in this case to apply the regulation in a manner that would further the acknowledged goals of the statute. Because a provider cannot obtain forbidden profits from contracting unless there is common ownership, application of the regulation in a case of common control should focus on the potential for unreasonable costs. Here, MCI contends, HAI's control came into being only when it could no longer affect the costs incurred by MCI.

The district court, in considering this argument, rejected its empirical premises. Because MCI and HAI entered into a long-term relationship, the court observed, the terms of their agreement will be refined, modified and enforced in light of experience and the parties' respective power through the years.[8] While the absence of any prior relationship between the parties is certainly relevant to the issue of control, it is insufficient to establish a *per se* rule barring application of the related party principle.

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[5](Footnote No. 4 is in the omitted material). As the court observed in *Fairfax Hospital Ass'n, Inc. v. Mathews, supra,* 459 F. Supp. at 433: Where "control," an issue of fact, is established, and only where it is established, the proscription of the regulations merely denies a double profit to a firm which is, in effect, dealing with itself. See also *Amercian Medical International, Inc. v. Sec. of HEW, supra,* 466 F. Supp. at 617-18.

[6]Courts have also suggested that 405.427 serves to limit unnecessary costs, or to define reimbursable costs in general. *Fallston General Hospital v. Harris, supra,* 481 F. Supp. at 1070; *Pasadena Hospital Ass'n, Ltd. v. United States,* 618 F.2d 728, 732-34 (Ct. Cl. 1980). In our view, however, this regulation does not implicate questions of necessity, either with respect to underlying transactions or with respect to particular procedures that are performed on Medicare patients. Nor do we agree that the Secretary's regulations may define "cost" as they see fit, for "cost" is a simple term of relatively fixed meaning. Moreover, if the Secretary possessed carte blanche authority to define costs, the explicit restrictions Congress imposed on reimbursable costs would be mere surplusage.

[7]Several courts have upheld the regulation against statutory and constitutional attacks. Upholding 42 C.F.R. 405.427 as consistent with 42 U.S.C. 1395x(v)(1)(A)(1976): *Schroeder Nursing Care, Inc. v. Mutual of Omaha Ins. Co.,* 311 F. Supp. 405, 410-11 (E.D. Wis. 1970); *Fairfax Hospital Ass'n, Inc. v. Mathews, supra,* 459 F. Supp. at 433; *Lockwood Hospital, Inc. v. Califano,* No. 76-H-240 (S.D. Tex. Feb. 10, 1978), *aff'd per curiam sub nom. Lockwood Hospital, Inc. v. Harris,* No. 78-1975 (5th Cir. Apr. 24, 1980).

Upholding 42 C.F.R. 405.427 as consistent with the Constitution: *Fairfax Hospital Ass'n, Inc. v. Mathews, supra,* 585 F.2d at 605-10; and *Chelsea Community Hospital v. Mich. Blue cross,* 436 F. Supp. 1050, 1061-63 (E.D. Mich. 1977).

[8]This fact distinguishes a case heavily relied on by MCI, *South Boston General Hosp. v. Blue Cross of Va.,* 409 F. Supp. 1380 (W.D. Va. 1976). See *id.* at 1383-84.

We agree with this reasoning. In our view, the power of control over MCI enjoyed by HAI since 1970 cannot be rigidly separated from the terms of their agreements. We recognize that a contrary conclusion was reached in *Northwest Community Hospital, Inc. v. Califano*, 442 F. Supp. 949 (S.D. La.1977). Like the district court in the present case, however, we find the *per se* rule adopted in that case unjustified by a management contractor's purported need to exercise control and inappropriate in light of our standards of review.

We hold, therefore, that the Commissioner's application of 42 C.F.R. 405.427 in this case did not violate the Medicare statute. The regulation, as applied, serves as a rough prophylactic rule barring the reimbursement of presumptively unreasonable costs. *See Mouring v. Family Publications Service, Inc.*, 411 U.S. 356, 372-74 (1973); *Fairfax Hospital Ass'n, Inc. v. Califano, supra,* 585 F.2d at 606-07.[9] We emphasize that, while the regulation relieves the Secretary of the need to determine the unreasonableness of particular costs, she must establish by substantial evidence the applicability of the regulation to the facts of each case. Here, as we have noted, the Secretary has satisfied this burden.

Accordingly, the judgment of the district court is affirmed.

MEDICAID PROGRAM

Pre-1977 Section 1909(b)(1) (42 U.S.C. 1396h(b)(1)—Medicaid—Offenses and Penalties—Kickbacks

HCFAR 80-5

U.S. v. Tapert, Medicare and Medicaid Guide (CCH) ¶ 30,540 (6th Cir.1980)

In return for payments from a laboratory, five physicians agreed to send patients' specimens to the laboratory under what was termed a "consulting agreement." The Federal government charged the physicians with soliciting and receiving kickbacks from the laboratory for referral of Medicaid patients under 42 U.S.C. 1396h(b)(1), as it existed before its amendment in 1977. This provision stated that:

[9]We are unpersuaded by MCI's argument that state corporation law and the Internal Revenue Code, each of which contains a different related organization principle, require a very narrow construction of the rule in the context of this case.

Whoever furnishes items or services to an individual for which payment is or may be made in whole or in part out of Federal funds under a State plan approved under this title and who solicits, offers, or receives any . . . kickback or bribe in connection with the furnishing of such items or services or the making or receipt of such payment . . . shall be guilty of a midemeanor. . . .

The physicians denied that this statute prohibited their conduct, and alleged that the statute was unconstitutional in that it was not sufficiently clear to give adequate notice to them that their conduct was illegal. The physicians rely also on the fact that Congress amended this section in 1977. Specifically, the physicians contend that, since they received no Federal funds for referring patients to the laboratory, their receiving money from the laboratories for the referrals did not violate 42 U.S.C. 1396h(b)(1).

Held, the payments the physicians received were kickbacks within the meaning of the pre-1977 statute. The Court construed the statutory term "kickbacks" to include a percentage payment for granting assistance by one in a position to open up or control a source of income. (This is the same definition of "kickbacks" as adopted and applied by the Seventh Circuit in *United States vs. Hancock*, 604 F.2d 699 (7th Cir. 1978).) The Court found the statute sufficiently clear to give adequate notice that receiving money from laboratories for referring Medicaid patients is illegal.

Further held, an amendment to an existing statute is not an acknowledgment by Congress that the original statute is invalid. It is a common and customary legislative procedure to enact amendments strengthening and clarifying existing laws.*

PHILLIPS, SENIOR CIRCUIT JUDGE:

These are consolidated appeals by five Detroit osteopathic physicians who were convicted by receiving kickbacks for sending urine and blood samples of their patients to Titan Laboratories (Titan) for analysis. All five of the physicians were enrolled in the Medicare and Medicaid programs and the charges for the laboratory analysis were paid by Titan out of Medicare and Medicaid funds. The district court held that the payments violated the original version of 42 U.S.C. 1396(b),[1] which was in effect during the years involved in this case. In 1977 Congress amended the statute so as to remove any possible doubt that conduct such as that involved in the present case violates the Act.[2]

The principal issues on this appeal are whether the information under which appellants were convicted charges a violation of the pre-1977 version of 42 U.S.C. 1396h(b)(1) (note one), and whether the statute is unconstitutional for vagueness. Then Chief District Judge Cornelia Kennedy, now a judge of this court, ruled that the payments to the doctors were kickbacks, that the information charges a violation of the statute, and that the statute is not invalid for vagueness. We affirm.

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*Because Congress amended section 1909(b)(1) (42 U.S.C. 1396(b)(1)) in 1977, this HCFA ruling applies only to kickbacks made while this statute was in effect.

I.

Apparently Titan initiated the arrangement for the kickbacks by having its representative contact one of the physicians.[3] In return for payments from Titan or one of its affiliates, the physician agreed to send his patients' specimens to Titan and to encourage his colleagues to do the same. Other physicians entered into similar agreements, which Titan described as "consulting" arrangements. This pattern of activity began in April 1974 and continued until January 1978.

Beginning in 1976, the physicians began depositing their Titan checks in an escrow fund for the purpose of acquiring an interest in Titan. The fund was administered by J.K.F. Inc., a corporation set up by the physicians to hold the Titan stock they proposed to buy. When the escrow fund reached $60,000, the physicians contributed an additional $15,000 and J.K.F. Inc. acquired a 40 percent interest in Titan.

On September 21, 1978, a federal grand jury returned a 37 count indictment against appellants, five other individuals and three Michigan corporations. On February 2, 1979, the Government filed a 42 count follow-up information charging appellants with soliciting and receiving Medicare and Medicaid kickbacks from Titan and associated entities. The information thereafter was amended. The version under which appellants were convicted is referred to in the record as the Amended Follow-Up Information.

Judge Kennedy denied the motions of appellants to dismiss the indictments. Thereafter, in a published opinion, she denied their motions for a rehearing. *United States v. Weingarden,* 468 F. Supp. 410 (E.D. Mich. 1979). In this opinion Judge Kennedy held that the pre-1977 version 42 U.S.C. 1396h(b)(1) prohibited the conduct charged in the information, and that the challenged statute was sufficiently clear to give to appellants adequate notice that their alleged conduct was illegal.

Thereafter, under a plea bargaining agreement, each of the appellants entered a plea of guilty to certain counts of the information applicable to him. The Government approved dismissal of the indictment.

II.

Prior to their guilty plea, the appellants gave notice that they intended to appeal the ruling of the district court on the applicability of 1396h(b)(1). To preserve the issue for appeal, they moved for arrest of judgement under Fed. R. Crim. P. 34 on the ground that the statute did not apply to their conduct and the district court, therefore, had no jurisdiction to accept their guilty pleas. This is the procedure approved by this court in *United States v. Heller,* 579 F.2d 990, 992-93, and n. 1 (6th Cir. 1978). See also *North Carolina v. Alford*, 400 U.S. 25,

37-38 (1970); *United States v. Cox,* 464 F.2d 927, 941 (6th Cir. 1972). The Government concedes that the alleged defects raised by appellants are jurisdictional and not waived by their guilty pleas. Consequently, the legal issue is properly before this court.

III.

* * *

[The counts against the five defendants, enumerated in the Information, and their pleas of guilty to those counts, have been deleted.—CCH]

IV.

In asserting that the statute was not sufficiently broad prior to the 1977 amendment to make their activities a criminal offense, and that the statute under which they were convicted is invalid for vagueness, appellants rely strongly upon the fact that Congress found it necessary to enact the 1977 amendment.

An amendment to an existing statute is not an acknowledgement by Congress that the original statute is invalid. It is a common and customary legislative procedure to enact amendments stengthening and clarifying existing laws.

The report of the House Committee on Ways and Means contains the following statement on the purpose of the 1977 amendment:

> Your committee bill would modify the penalty provisions in *existing law* which relate to those persons providing services under medicare and medicaid.
>
> *Existing law* provides specific penalties under the medicare and medicaid programs for certain practices that long have been regarded by professional organizations as unethical, which are unlawful in some jurisidictions, and which contribute significantly to cost of the programs. Such practices as the submission of false claims, or the soliciting, offering, or *acceptance of kickbacks or bribes, including rebates or* [*sic*] *a portion of fees or charges for patient referrals, are misdemeanors under present law. . .*
>
> Recent hearing and reports, however, indicate that such penalties have not proved adequate deterrents against illegal practices by some individuals who provide services under medicare and medicaid. In addition, these misdemeanor penalties appear inconsistent with existing Federal criminal code sanctions which make similar actions punishable as felonies. Also, it has been brought to the attention of the committee by the U.S. Attorney's offices which have utilized these Social Security Act sanctions in the prosecution of medicare and medicaid fraud cases that the existing language of these penalty statutes is unclear and needs clarification.
>
> Your committee's bill would strengthen the penalty provisions in *existing law* which relate to persons providing services under medicare and medicaid. . .
>
> In addition, the bill would *clarify and restructure* those *provisions in existing law* which define the types of financial arrangements and conduct to be classified as illegal under medicare and medicaid. (Emphasis added.) H.R. Rep. No. 95-393 (II), 95th Cong., 1st Sess. *reprinted in* (1977) U.S. Code Cong. & Ad. News 3039, 3055.

We agree with the definition of "kickbacks" adopted and applied by the Seventh Circuit in *United States v. Hancock*, 604 F.2d 699 (7th Cir. 1978). We follow that decision in affirming the decision of the district court that appellants have entered pleas of guilty under an Information charging them with violations of a valid statute which made their conduct a criminal offense. The record demonstrates to our satisfaction that the payments which the appellants admitted receiving were "kickbacks" within the meaning of the statute.

We choose to follow the Seventh Circuit in *Hancock*, rather than *United States v. Porter,* 591 F.2d 1048 (5th Cir. 1979). The reasons for this conclusion are stated well by Judge Kennedy in her published opinion. 468 F.Supp. at 412-15.

Appellants contend that they did not "furnish" the services in connection with which they received payments, and that the Information does not charge an offense. These and all other contentions made by appellants have been considered and found to be without merit.

The convictions are affirmed.

[*Concurring opinion*]

JONES, CIRCUIT JUDGE, concurring: I agree that the term "kickback" should be defined to include "a percentage payment for granting assistance by one in a position to open up or control a source of income." *United States v. Hancock*, 604 F.2d 999, 1002 (7th Cir. 1978). The United States has an important interest in securing the honest administration of federally funded programs. *United States v. Thompson*, 366 F.2d 167 (6th Cir.), *cert. denied,* 385 U.S. 973 (1966). I write separately to discuss a substantial issue of first impression concerning the construction of 42 U.S.C. 1396h(b)(1) (1972): Is a physician, who provides services to Medicaid patients and who receives illegal kickbacks from laboratories for the referral of those patients, for which referrals federal funds do not reimburse the doctor or the laboratory, a person who "*furnishes* items or services to an individual *for which* payment is or may be made in whole or part out of Federal funds . . . *and* who . . . receives any (1) kickback . . . *in connection* with the furnishing of such items or services . . .?" I concur with the majority's affirmative answer.

The language of the amended informations and the guilty pleas, as thoroughly reported in the majority opinion, define the facts of the case.[1] The defendants were charged with and pleaded guilty to receiving payments in various forms from a laboratory for patient referrals. The informations allege that the defendants "obtained services" from a laboratory, for which services Medicaid would pay in part, and that the defendants received kickbacks in connection with these services. Consequently, the relevant services for which federal funds were paid are the tests performed by the laboratory. The record

also establishes that the defendants were reimbursed by Medicaid for their treatment of the same patients referred to the laboratories.

The facts raise two questions of statutory interpretation: 1) did the physicians "furnish" the laboratory services; and 2) were the kickbacks paid "in connection with" the laboratory services rather than just the patient referrals? Defendants argue that they did not "furnish" the laboratory services, since the laboratory actually performed the tests. They point out that their services were reimbursed separately from the laboratory tests. Second, they argue that the kickbacks were paid "in connection with" the patient referrals rather than any service for which Medicaid funds were paid. They declare that the kickbacks did not affect their treatment of patients or the laboratory's performance of tests.

It is fair to say that physicians in Michigan in 1976-1977 furnished the laboratory services to their patients. The physicians took the specimens and sent them to a laboratory. A laboratory could act only on orders from the physicians. Mich. Comp. Laws Ann 325.81(b), 325.89(b), repealed by Mich. Comp. Laws Ann 333.20501 *et seq.* (1978); *cf* 42 C.F.R 405.1316(e) (Medicare regulations). The laboratory could report the test results only to the physicians, unless they instructed otherwise. Mich. Adm. Code R. 325.2353(2)(Rule 53); *cf.* 42 C.F.R. 405.1316(g) (Medicare regulations). The physicians bore the responsibility of interpreting the test data. In short, the physicians did everything but actually perform the clinical tests. Under these circumstances, by interpreting the word "furnish" according to its common usage to mean "supply or provide", I would hold that the physicians did "furnish" the laboratory services.

The physicians received the kickbacks "in connection with" the laboratory services. The statute is satisfied if there is a logical relationship between the kickbacks and the services for which federal funds were paid. In our case, the kickbacks were an agreed part of the performance of the laboratory services. The relationship between the physicians and the laboratory was formed around the payment of the kickbacks. The physicians chose to refer patients to a specific laboratory because of the negotiated kickback payments. The phrase "in connection with" has a sufficiently broad meaning in common parlance to conclude that the kickbacks were received "in connection with" the laboratory services.

The legislative history bolsters my interpretation of 1396h(b)(1) as enacted in 1972. Congress intended to prohibit in the administration of the Medicaid program any practices which were unethical or were proscribed by state law. H.R. Rep. No. 92-231, 92d Cong., 2d Sess., *reprinted in* [1972] U.S. Code Cong. & Ad. News 4989, 5007, 5093, 5308. The physicians' receipt of kickbacks for patient referrals to the laboratory is forbidden by both Section 21 of the Code of Ethics of the Michigan Association Osteopathic Physicians and Surgeons and by State statute, Mich. Comp. Laws Ann 445.162. Similarly, a laboratory is prohibited from soliciting business by paying kickbacks. Mich. Comp. Laws Ann.

333.20525(c) (1978). Since the language of the statute permits, 1396h(b)(1) should be interpreted to effectuate congressional intent. *Barrett v. United States,* 423 U.S. 212 (1976); *United States v. Tarter,* 522 F.2d 520 (6th Cir. 1975). The ordinary meaning of the statutory language and the 1972 legislative history compel the conclusion that the physicians' receipt of kickbacks under the circumstances in this case is a violation of 1396h(b)(1).

Finally, because the ordinary meaning of the plain language of 1396h(b)(1) would have notified the defendants that their conduct was unlawful, the statute is not unconstitutionally vague, *United States v. Hancock,* 604 F.2d at 1002.

Accordingly, I concur with the opinion and judgment of the majority.

—Footnotes—

[1](b) Whoever furnishes items or services to an individual for which payment is or may be made in whole or in part out of Federal funds under a State plan approved under this title [42 USCA 1396-1396d, 1396f-1396i] and who solicits, offers, or receives any—

(1) kickback or bribe in connection with the furnishing of such items or services or the making or receipt of such payment, or

(2) rebate of any fee or charge for referring any such individual to another person for the furnishing of such items or services.

shall be guilty of a misdemeanor and upon conviction thereof shall be fined not more than $10,000 or imprisoned for not more than one year, or both.

[2]The amended 1396h(b)(1) is as follows:

(b)(1) Whoever solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under this subchapter, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under this subchapter.

shall be quilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

(2) Whoever offers or pays any remuneration (including any kickbacks, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—

(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under this subchapter, or

(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing ,or ordering any good, facility, service, or item for which payment may be made in whole or in part under this subchapter.

shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

(3) Paragraphs (1) and (2) shall not apply to—

(A) a discount or other reduction in price obtained by a provider of services or other entity under this subchapter if the reduction in price is properly disclosed and

appropriately reflected in the costs claimed or charges made by the provider or entity under this subchapter; and

(B) any amount paid by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services.

[3]See *United States v. Shermetaro,*—F.2d—(No. 79-5148, 6th Cir. 1980), in which this court affirmed the conviction of one of the parties to this scheme under 18 U.S.C. 371 for conspiracy to defraud the United States by obstructing the collection of income taxes from Titan Laboratories.

[*Concurring opinion*]

[1]According to my construction of 1396h(b)(1), the amended informations do state an offense. In his zeal to uphold the guilty pleas, the Assistant United States Attorney argued seriously that this court should consider the amended informations to have been informally amended by oral argument and by his response to the defendants' motion to dismiss the informations. Further, he contended that the district court had *implicitly* granted leave for this informal second amendment. The government's position is not supported in the record and is an attempt to play "fast and loose" with the established rules of criminal procedure and principles of due process. Such overly zealous advocacy should be tempered. In other respects, the Assistant United States Attorney prepared a fine brief.

Part II, Listing of Selected Court Decisions Published as Rulings

Part III, Numeric Index of Final Decisions Rendered by the Administrator of Health Care Financing Administration on PRRB Decisions

79-D77—Counting of inpatient days—Labor/delivery room. (1/16/80)

79-D78—Cost of educational activities—Joint educational activities. (1/17/80)

79-D79—Pathology expenses. (1/18/80)

79-D80—Administrative and general costs; Gifts and grants; Transporter's costs; Interest expense. (1/23/80)

79-D81R—Special care units. (3/7/80)

79-D83—Limitations on coverage of costs. (1/27/80)

79-D86—Return on equity capital to non-profit provider, Hill-Burton grants. (2/15/80)

79-D87—Special care units, Interest expense; Depreciation. (2/14/80)

79-D94—Special care units. (2/13/80)

79-D95—Return on equity capital to non-profit providers, Charity allowance & bad debts. (2/15/80)

79-D98—Special care units, Admitting department costs. (2/26/80)

79-D99—Consulting Fees; Physical therapy costs, Advertising costs—yellow pages; Data processing costs; Organization costs, Consulting fees. (3/3/80)

80-D1—Data processing costs; Administrator's compensation; Organizational costs; Advertising—yellow pages; Parking expenses. (3/6/80)

80-D2—Abandoned acquisition costs; Charitable contributions; Life insurance costs; Stock maintenance; Aircraft equity; Goodwill. (3/6/80)

80-D3—Special care units; Ancillary and routine costs; Limitation on coverage of costs. (3/8/80)

80-D4—Transportation costs—auto; Administrator's compensation and assistant administrator's compensation; Organizational costs. (3/3/80)

80-D5—Cost of educational activities—Joint educational activities. (4/15/80)

80-D6—Cost of educational activities—Joint educational activities. (4/15/80)

80-D9—Hill-Burton grants. (4/14/80)

80-D21—Depreciation; Recapture of accelerated depreciation. 6/17/80)

80-D28—Special care units. (7/8/80)

80-D29—Special care units. (6/26/80)

80-D30—Goodwill; Stock maintenance. (7/21/80)

80-D35—Special care units; Malpractice insurance. (7/29/80)

80-D36—Special care units. (7/17/80)

80-D40—Limitations on coverage of costs. (8/22/80)

80-D43—Unrecovered costs of visitors' meals; Taxes. (9/3/80)

80-D45—Counting of inpatient days—labor/delivery room; Hill-Burton grants. (9/11/80)

80-D46—Leased hospital departments; Hill-Burton grants. (9/11/80)

80-D47—Hill-Burton grants. (9/11/80)

80-D48—Return on equity capital—inclusion of assets and personal guarantees. (9/11/80)

80-D49—Special care units. (9/16/80)

80-D50—Reasonableness of salaries; Automobile expense; Accounting fees. (9/22/80)

80-D51—Counting of inpatient days—labor/delivery room; Hill-Burton grants. (9/22/80)

80-D54—Life insurance premiums; Diagnostic services. (9/23/80)

80-D56—Limitations on coverage of costs. (9/29/80)

80-D58—Hill-Burton grants. (9/29/80)

Numeric Index of the Administrator Health Care Financing Administration Decisions to Remand PRRB Decisions

No cases were remanded by the Administrator during the period January 1, 1980 through September 30, 1980.

Part IV, Listing of Published Health Care Financing Administration Program Regulations January-September 1980

The following amendments and additions to HCFA regulations have been published in the *Federal Register:*

1. Notice—Statewide Professional Standards Review Council of Louisiana (45 FR 845, January 3, 1980)

2. Notice—National Professional Standards Review Council meeting (45 FR 2399, January 11, 1980)

3. Notice—Pharmaceutical Reimbursement Board; Proposed MAC's and Announcement of Public Hearing (45 FR 3972-3974, January 21, 1980)

4. Notice—Quality Control System Error Rate (45 FR 6331-6333, January 25, 1980)

5. 42 CFR Part 431 and 45 CFR Part 205—Fiscal Disallowance for Erroneous Payments in Aid to Families with Dependent Children and Medicaid Programs: Calculating Reduction in FFP for Incorrect Payment by States After September 1980 (45 FR 6326-6331, January 25, 1980)

6. 42 CFR Parts 433, 435, and 436; 45 CFR Parts 302, 304, and 306—Assignment of Benefits; Collection of Medical Support and Payments (45 FR 8982-8988, February 11, 1980)

7. Notice—National Professional Standards Review Council; Meeting (45 FR 9769-9770, February 13, 1980)

8. Notice—Final Maximum Allowable Cost Determinations (45 FR 10032-10035, February 14, 1980)

9. Notice—Schedule of Limits on Home Health Agency Costs per Visit (45 FR 10450-10456, February 15, 1980)

10. 45 CFR Part 95—Automatic Data Processing Equipment and Services; Conditions for Federal Financial Participation (45 FR 10793-10794, February 19, 1980)

11. 42 CFR Parts 455 and 474—Imposition of Sanctions on Health Care Practitioners and Providers of Health Care Services; Program Integrity (45 FR 11436-11441, February 20, 1980)

12. 42 CFR Part 463—Review Responsibility and Authority of Professional Standards Review Organizations (PSRO's); PSRO Review of Intermediate Care Facilities if Medicaid State Agency Review is Ineffective or Inefficient (45 FR 11807-11811, February 22, 1980)

13. Notice—Coverage of Oxygen for Use in a Patient's Home (45 FR 11912-11913, February 22, 1980)

14. 42 CFR Part 447—Payments for Long-Term Care Facility Services (45 FR 11806-11807, February 22, 1980)

15. Notice—Health Financing Research and Demonstration Grants; Availability (45 FR 12362-12364, February 25, 1980)

16. 42 CFR Part 405—Payment for Services of Independent Rural Health Clinics (45 FR 13075-13076, February 28, 1980)

17. Notice—National Professional Standards Review Council; Request for Nomination of Members (45 FR 13537, February 29, 1980)

18. 42 CFR Part 433—Medicaid Management Information Systems—Additional Data Requirements (45 FR 14211-14214, March 5, 1980)

19. Notice—Schedule of Target Reimbursement Rates for Institutions Furnishing Home Dialysis Supplies, Equipment, and Support Services (45 FR 14249-14251, March 5, 1980)

20. Notice—Revision of Subpart S—Certification Procedures for Providers and Suppliers of Services (45 FR 14900-14901, March 7, 1980)

21. Notice—Reimbursement of Hospital-Based Physicians (45 FR 1550-1554, March 11, 1980)

22. Notice—Statewide PSRO Council of Missouri; Request for Nominations for Public Member Positions on the Council (45 FR 16337-16338, March 13, 1980)

23. Notice—Reimbursement of Hospital-Based Physicians (45 FR 18927, March 24, 1980)

24. 42 CFR Part 405—Federal Health Insurance for the Aged and Disabled; Quality Control and Proficiency Testing Standards for Laboratories in Medicare Hospitals (45 FR 20802, March 31, 1980)

25. Notice—Proposed Schedule of Limits on Hospital Inpatient General Routine Operating Costs for Cost Reporting Periods Beginning on or after July 1, 1980 (45 CFR 21582-21588, April 1, 1980)

26. 42 CFR Parts 405, 442, and 489—Provider Agreements: Redesignation and Rewrite of Medicare Regulations, Effective Dates; Effect of Change in Ownership (45 FR 22933-22941, April 4, 1980)

27. 42 CFR Part 405—Conditions for Coverage of Suppliers of ESRD Services; Revocation of Requirements for Emergency Generator and Ground Fault Interrupters (45 FR 24838-24839, April 10, 1980)

28. 42 CFR Subchapter C—Miscellaneous Corrections (45 FR 24878-24890, April 11, 1980)

29. Notice—Pharmaceutical Reimbursement Board; Final Maximum Allowable Cost Determination (45 FR 25141-25142, April 14, 1980)

30. Notice—National Professional Standards Review Council; Meeting (45 FR 25143, April 14, 1980)

31. 42 CFR Part 405—Recodification of Medicare Regulations (45 FR 25829-25830, April 16, 1980)

32. 42 CFR Part 405—Prohibition of Reassignment of Claims by Providers and Suppliers (45 FR 26699-26705, April 21, 1980)

33. Notice—42 CFR Parts 405, 440, 456, and 482—Hospital Utilization Review (45 FR 29535, May 2, 1980)

34. Notice—Maximum Allowable Cost Program; Intent to Set MAC Limits (45 FR 29639-29641, May 5, 1980)

35. 42 CFR Parts 447 and 462—Medicaid Provider Records and Grants to PSRO: Technical Amendments (45 FR 30634-30635, May 9, 1980)

36. 42 CFR Part 420—Disclosure of Provider Information and Access to Provider Records (45 FR 30634, May 9, 1980)

37. Notice—Schedules of Guidelines for Respiratory Therapy Services (45 FR 37527-37530, June 3, 1980)

38. Notice—Medicare and Medicaid Programs; Schedule of Limits on Home Health Agency Cost Per Visit (45 FR 38014-38022, June 5, 1980)

39. 42 CFR Chapter IV—Fiscal Year 1980 Regulation Plan (45 FR 40050-40060, June 12, 1980)

40. Notice—National Professional Standards Review Council; Meeting (45 FR 41074, June 17, 1980)

41. Notice—Schedule of Limits on Skilled Nursing Facility Inpatient Routine Service Costs (45 FR 41292-41301, June 18, 1980)

42. Notice—Clarification of Urban Location Classification in New England (45 FR 41218-41219, June 18, 1980)

43. 42 CFR Part 447—Medicaid Overpayment Reporting Requirements (45 FR 41661, June 20, 1980)

44. Notice—Schedule of Limits on Hospital Inpatient General Routine Operating Costs of Cost Reporting Periods Beginning on or after July 1, 1980 (45 FR 41868-41880, June 20, 1980)

45. 42 CFR Part 405—Reimbursement of Hospital-Based Physicians (45 FR 41635, June 20, 1980)

46. 42 CFR Part 421—Intermediary Nominations, Contracts, Evaluations and Notices (45 FR 42174-42183, June 23, 1980)

47. Notice—Medicare Program; Statistical Standards for Evaluating Intermediary Performance During Fiscal Year 1980 (45 FR 42184-42188, June 23, 1980)

48. Notice—Schedule of Limits on Home Health Agency Costs per Visit (45 FR 42038, June 23, 1980)

49. 42 CFR Part 455—Medicaid Agency Fraud Detection and Investigation Program: Verification of Services (45 FR 43441, June 27, 1980)

50. Notice—Economic Index for Physicians' Services for the Period July 1, 1980 through June 30, 1981 (45 FR 43475, June 27, 1980)

51. 42 CFR Part 405—Payment for Durable Medical Equipment (45 FR 44287-44292, July 1, 1980)

52. 42 CFR Part 460—Professional Standards Review; Redesignation of PSRO Areas in California (45 FR 48620-48622, July 21, 1980)

53. 42 CFR Parts 405, 442, and 447—Protection of Patients' Funds (45 FR 49440-49447, July 24, 1980)

54. Notice—Adoption of the National Bureau of Standards Fire Safety Evaluation System for Health Care Facilities (45 FR 50264-50265, July 28, 1980)

55. 42 CFR Parts 405, 422, and 483—Conditions of Participation for Skilled Nursing and Intermediate Care Facilities (45 FR 50373, July 29, 1980)

56. 42 CFR Part 455—State Medicaid Fraud Control Units (45 FR 51559, August 4, 1980)

57. 42 CFR Part 405—Reimbursement for Costs for Approved Internship and Residency Programs (45 FR 51783-51787, August 5, 1980)

58. Notice—Supplemental Health Insurance Panel—Evaluation of State Regulatory Programs for Medigap Policies (45 FR 51923-51924, August 5, 1980)

59. Notice—Exclusion of Heart Transplantation Procedures from Medicare Coverage (45 FR 52296-52297, August 6, 1980)

60. 42 CFR Part 405—Definition and Reimbursement of Hospital Intensive Care Type Units (45 FR 54757-54760, August 18, 1980)

61. Notice—Schedule of Limits on Home Health Agency Costs Per Visit (45 FR 54864-54867, August 18, 1980)

62. Notice—National Professional Standards Review Council; Meeting (45 FR 56193, August 22, 1980)

63. 42 CFR Part 405—Reimbursement for Radiological Services Furnished to a Hospital Inpatient by a Physician in the Field of Radiology (45 FR 56060-56062, August 22, 1980)

64. Notice—Schedule of Guidelines for Respiratory Therapy Services (45 FR 56446-56447, August 25, 1980)

65. 45 CFR Part 405—Cost Reporting Requirements for Home Health Agencies (45 FR 57126, August 27, 1980)

66. Notice—Health Financing Research and Demonstration Grants; Special Solicitation (45 FR 58090-58096, August 29, 1980)

67. 42 CFR Part 405—Extension of Time Periods for End Stage Renal Disease (ESRD) Facilities to Achieve Conditional and Unconditional Status (45 FR 58123-58125, September 2, 1980)

68. Notice—Maximum Allowable Cost Program; Intent to Set MAC Limits (45 FR 58409, September 3, 1980)

69. Notice—Schedule of Limits on Skilled Nursing Facility Inpatient Routine Service Costs (45 FR 58699-58709, September 4, 1980)

70. Notice—Reimbursement for Costs of Approved Internship and Residency Programs (45 FR 59153, September 8, 1980)

71. Notice—Schedule of Limits on Skilled Nursing Facility Inpatient Routine Service Costs (45 FR 61369-61370, September 16, 1980)

72. Notice—Pharmaceutical Reimbursement Board, Intent to Set MAC Limits (45 FR 62560, September 19, 1980)

Part V, Health Care Financing Administration Index of Administrative Manuals and Instructions

The Freedom of Information Act, as amended (Public Law 93-502) requires each government agency to make available for public inspection and copying all administrative manuals and instructions to staff which affect any member of the public. In order to give the public an understanding of what material is thereby available, agencies must provide a regularly updated index of pertinent titles. This index itself, like the manuals and other materials it lists, is required by law to be available to the public for inspection and copying upon request.

The following Index represents an update of Medicaid and PSRO instructions and issuances from January through September 1980. It also includes a listing and description of the Medicare manuals that affect the public.

The Index will be maintained in all Health Care Financing Administration Regional Offices where it may be examined by members of the public. The office will supply photocopies of selected pages upon request. (There may be a fee charge for this service, depending on the quantity of material requested.)

Any questions regarding this index should be made in writing to:

HCFA
Bureau of Program Policy
6325 Security Blvd.
Baltimore, Maryland 21207

MEDICAID

ACTION TRANSMITTALS

Action Transmittals are designed to transmit policies, regulations and State plan preprints for administering the Medicaid program. A numeric listing of the Action Transmittals issued from January through September 1980 follows:

AT-80-1 —Practitioners, Providers, or Other Health Care Suppliers Suspended, Excluded, or Terminated from the Medicare and Medicaid Programs

AT-80-2 —Title XIX, Social Security Act, §1903(g)—Utilization Control (UC) Validation Survey for the Quarter Ending 12-31-79

AT-80-3 —Practitioners, Providers, or Other Health Care Suppliers Suspended, Excluded, Terminated from the Medicare and Medicaid Programs

AT-80-4 —Quality Control System Error Rate

AT-80-5 —Request for Medicaid Quality Control Review Schedule Information for the July-December 1978 Review Period

AT-80-6 —Third Party Liability; Assignment of Benefits; Collection of Medical Support and Payments

AT-80-7 —Preprinted State Plan Amendments on (1) Assignment of Rights to Medical Care Support and Payments as a Condition of Eligibility, and (2) Cooperative Arrangements with Other State Agencies for Enforcement of Rights to Support and Collection of Assigned Payments

AT-80-8 —Monthly Report on Suspensions, Exclusions, Terminations, Withdrawals, or Reinstatements of Physicians/Practitioners, Providers, and/or Other Suppliers of Health Care Services.

AT-80-9 —Recent Settlement Agreement in *Underwood* vs. *Harris* Related to Medicaid Eligibility

AT-80-10 —1) Medicaid Quality Control (MQC) Review of AFDC-QC and SSI-AQ Ineligible Cases

AT-80-11 —Upper Limits of Medicaid Payments for Long-Term Care Facility Services

AT-80-12 —Title XVIII, Rural Health Clinic Services; Title XIX, Rural Health Clinic Services

AT-80-13 —Limitation on Payment or Reimbursement for Drugs

AT-80-14 —Revision to MQC Manual on Four Months Extended Coverage Code Methodology

AT-80-15 —Title XIX, Social Security Act: Medicaid Management Information Systems

AT-80-16 —Recission of AT-79-59 Applying Medicare Home Health Agency Cost Limits to Title XIX Reimbursement

AT-80-17 —Preprinted State Plan Amendments on (1) Assignment of Rights to Medical Care Support and Payment as a Condition of Eligibility, and (2) Cooperative Arrangements with Other State Agencies for Enforcement of Rights to Support and Collection of Assigned Payments

AT-80-18 —Medical Assistance Manual: Services & Payment in Medical Assistance Programs; Early & Periodic Screening, Diagnosis, & Treatment (EPSDT) of Eligible Individuals Under Age 21; Reports; Quarterly Child Health Status Report (HCFA-156)

AT-80-19 —Monthly Report of Physicians/Practitioners, Providers, and/or Other Suppliers of Health Care Services Suspended, Excluded, Terminated, Reinstated, or Where Effectuated, Sanction was Withdrawn

AT-80-20 —Utilization Review Procedures for Hospitals and for Facilities or Programs that Provide Inpatient Psychiatric Services to Medicaid Recipients Under 21 Years of Age

AT-80-21 —Requirements for Certification of Medicare and Medicaid Long Term Care Facilities with Repeat Deficiencies

AT-80-22 —Medicaid Reasonable Cost Payment for Inpatient Hospital Services Title XVIII, Social Security Act: Medicare Reasonable Cost Payment for Inpatient Hospital Services

AT-80-23 —Instructions Regarding EPSDT Monthly Lists for Penalty Monitoring Sample Purposes

AT-80-24 —Submission of the State Medicaid Cost Report as a Supplement to Plan Attachment 4.19D

AT-80-25 —Provider Agreements: Effective Dates; Effect of Change in Ownership

AT-80-26 —Substantial Gainful Activity Earnings Guidelines for 1980

AT-80-27 —Medicare Reimbursement of Hospital-Based Physicians

AT-80-28 —Annual Hospital Report

AT-80-29 —Preprinted State Plan Amendment on Provider Agreements—Effective Dates and Change of Ownership

AT-80-30 —Clarification of Options for Reporting MQC 6-Month Summary Data and Revision of Review Schedule Edits

AT-80-31 —Sec. 1903(g) of the Social Security Act (42 U.S.C 1396b(g)—Utilization Control Validation Study

AT-80-32 —Instructions for adjusting hospital and skilled nursing facility interim payments for malpractice costs

AT-80-33 —Revisions to the Instructions for Preparation of the Quarterly Report of Abortions (Form HCFA 64.9b) for the Medical Assistance Program Approved Under Title XIX

AT-80-34 —Medicaid Program—Miscellaneous Corrections

AT-80-35 —Medicaid Reimbursement Survey

AT-80-36 —Clarification of Exhibit A-3, Number 39, Rounding Policy for Edit Checks for Consistency of Entries, MQC Manual 4000

AT-80-36A —Clarification of Exhibit A-3, Number 39, Rounding Policy for Edit Checks for Consistency of Entries, MQC Manual 4000

AT-80-37 —Affirmation of continuing reporting requirements for quarterly statements of financial plans (OA-25A and OA-25.5)

AT-80-38 —Revision of Complete Text of Preprinted State Plans

AT-80-39 —State Agencies Administering Medical Assistance Programs

AT-80-40 —Monthly Report of Physicians/Practitioners, Providers and/or Other Suppliers of Health Care Services Suspended, Excluded, Terminated, Reinstated, or Where Effectuated, Sanction was Withdrawn

AT-80-41 —AFDC and SSI Strata Cases Which Do Not Appear on the Medicaid Eligibility File

AT-80-42 —Change in Medicaid Quality Control (MQC) Methodology

AT-80-43 —Common Medicaid—Medicare Audit Requirements for Hospitals

AT-80-44 —1) Liability Errors Applicable to All Strata;
2) States with Administrative Periods Less than 60 Days

AT-80-45 —Titles XVIII and XIX of the Social Security Act: Prohibition Against Payment for Less Than Effective Drugs

AT-80-46 —The Periodic Interim Payment Method of Reimbursement Under Title XIX

AT-80-47 —Revised Reporting Requirement for Quarterly Statements of Financial Plan (Old OA-25) & Quarterly Estimate of Expenditures (HCFA-65)

AT-80-48 —Monthly Report of Physicians/Practitioners, Providers, and/or Other Suppliers of Health Care Services Suspended, Excluded, Terminated, Reinstated, or Where Effectuated, Sanction was Withdrawn.

AT-80-49 —Title XVIII, Social Security Act: Medicare Program—Hospital Insurance Entitlement and Benefits: Recodification of Regulations

AT-80-50 —Title XIX, Social Security Act: Medicaid Eligibility of Recent Cuban/Haitian Entrants

AT-80-51 —Addition of Coverage Codes to Medicaid Quality Control (MQC) Manual and Revision of Associated Review Schedule Edits

AT-80-52 —Title XIX, Social Security Act: Medicaid Payment for Inpatient Hospital Services; Title XVIII, Social Security Act

AT-80-53 —Title XIX, Social Security Act: Medicaid Agency Fraud Detection and Investigation Program: Verification of Services

AT-80-54 —Instructions Regarding EPSDT Monthly Lists for Penalty Monitoring Sample Purposes

AT-80-55 —Monthly Report of Physicians/Practitioners, Providers, and/or Other Suppliers of Health Care Services Suspended, Excluded, Terminated, Reinstated, or Where Effectuated, Sanction was Withdrawn

AT-80-56 —Title XIX, Social Security Act: Court Order Affecting Deeming Policies in 209(b) States, Guam, Puerto Rico. and the Virgin Islands

AT-80-57 —Medicaid Quality Control (MQC) Sample Size Change

AT-80-58 —Revision of Preprinted Plan Material for State Medicaid Programs ATTACHMENT 2.6-C, pages 6 Eligibility Conditions and Requirements for the Medically Needy

AT-80-59 —Title XIX, Social Security Act: Revised Reporting for Quarterly Statements of Financial Plan (OA-25) and Quarterly Estimate of Expenditures (HCFA-65)

AT-80-60 —Revision of Complete Text of Preprinted State Plan —CORRECTION

AT-80-61 —Protection of Patients' Funds

AT-80-62 —Protection of Patients' Funds

AT-80-63 —Update to Medicaid Quality Control Manual dated February 1978

AT-80-64 —Title XIX, Social Security Act: Reimbursement for Costs of Approved Internship and Residency Programs

AT-80-65 —Monthly Report of Physicians/Practitioners, Providers, and/or Other Suppliers of Health Care Services Suspended, Excluded, Terminated, Reinstated, or Where Effectuated, Sanction was Withdrawn.

AT-80-66 —Clarification of Medicaid Quality Control (MQC) Review Schedule Coding and Addition of Corresponding Edit

AT-80-67 —Clarification of Medicaid Quality Control Review Completion and Reporting Deadlines

AT-80-68 —Title XIX, Social Security Act, Section 1903(g)—Utilization Contol (UC): Certification and Recertification Requirements

AT-80-69 —Instructions for Completing the Medicaid Quality Control (MQC) Review Schedule

AT-80-70 —Providing Medicare Claims Information to Title XIX Agencies

AT-80-71 —Monthly Report of Physicians/Practitioners, Providers, and/or Other Suppliers of Health Care Services Suspended, Excluded, Terminated, Reinstated, or Where Effectuated, Sanction was Withdrawn

INFORMATION MEMORANDA

Information Memoranda are Medicaid issuances used for one time requests for information, and for transmission of information, such as proposed rules and conference dates, that need not be retained. A numeric listing of the Information Memoranda issued from January through September 1980 follows:

HCFA-IM-80-1 —Seminar on Cost-Related Reimbursement for Long Term Case (1/15/80)

HCFA-IM-80-2 —List of Single State Agency Directors and Medical Assistance Unit Directors (1/15/80)

HCFA-IM-80-3 —Workshop on Management Information for Medicaid (2/5/80)

HCFA-IM-80-4 —Index of ATs and Information Memorandums Written to Date Which Change or Clarify Medicaid Quality Control Policy (2/6/80)

HCFA-IM-80-5 —National Conference on Medicaid Management Information Systems (MMIS)—Benefits to Management Louisville, Kentucky, April 14-16, 1980 (2/11/80)

HCFA-IM-80-6 —Office of Child Health Clearinghouse/Information Utilization System—Sharing Materials Developed by the Data County EPSDT Demonstration Project (2/14/80)

HCFA-IM-80-7 —Twelfth Annual Conference of State Medicaid Directors (3/7/80)

HCFA-IM-80-9 —Physician Certification to Override Maximum Allowable Cost Limits on Prescribed Drugs (3/26/80)

HCFA-IM-80-10 —Technical Assistance Document (TAD) for State Medicaid Agency Monitoring of PSROs (4/3/80)

HCFA-IM-80-11 —Guide to Adolescent Health Care—EPSDT (4/25/80)

HCFA-IM-80-12 —Symposium on Integration of Survey and Inspection of Care (4/28/80)

HCFA-IM-80-13 —Implementation of EPSDT QC Reviews 4/29/80)

HCFA-IM-80-14 —Independent Professional Review and Medical Review Teams Training Session—INFORMATION (4/30/80)

HCFA-IM-80-15 —Independent Professional Review and Medical Review Teams Training Session—INFORMATION (4/30/80)

HCFA-IM-80-16 —List of Single State Agency Directors and Medical Assistance Unit Directors (5/14/80)

HCFA-IM-80-17 —Common Claim Form for Physician/Supplier Services (5/23/80)

HCFA-IM-80-18 —Program Validation Reviews (5/28/80)

HCFA-IM-80-19 —Conference—Corrective Action for Medicaid Eligibility Error Reduction (6/6/80)

HCFA-IM-80-20 —Training Sessions on Completion of the Revised Form HCFA-25 "State Agency Budget Forecast and Quarterly Grant Requirements" (6/26/80)

HCFA-IM-80-21 —Conference—Third Party Resource Identification & Verification (7/24/80)

HCFA-IM-80-22 —Model Memorandum of Understanding Between End-Stage Renal Disease Medical

Review Boards and Professional Standards Review Organizations (8/12/80)

HCFA-IM-80-23 —Implementation of Medicaid Cost Report Evaluation Program (CREP) (8/19/80)

HCFA-IM-80-24 —Preparation for the Onset of EPSDT QC Reviews (8/25/80)

HCFA-IM-80-25 —Acceptable State Documentation Regarding EPSDT Informing and Services (8/25/80)

HCFA-IM-80-26 —EPSDT Sampling (8/26/80)

HCFA-IM-80-27 —Improving Consistency, Accuracy and Comparability of Diagnosis and Procedure Labeling Systems (8/29/80)

HCFA-IM-80-28 —Third Party Liability Multi-State Workshop (8/29/80)

HCFA-IM-80-29 —List of Single State Agency Directors and Medical Assistance Unit Directors (9/10/80)

HCFA-IM-80-30 —EPSDT QC Requirements for Cases Where the AFDC Payment has been Held or Suspended (9/10/80)

HCFA-IM-80-31 —Overview of the Federal Approvals Process for State Medicaid Management Information Systems

HCFA-IM-80-32 —EPSDT Quality Control Reviews of Recipients Due for Rescreening When the Period Ends at Age 21

REGIONAL OFFICE MANUAL (ROM)

Part 1 — General (HCFAPub. 23-1)
Part 2 — Medicare (HCFA-Pub. 23-2)
Part 3 — Program Integrity (HCFA-Pub. 23-3)
Part 4 — Standards and Certification (HCFA-Pub. 23-4)
Part 5 — Professional Standards Review (HCFA-Pub. 23-5)
Part 6 — Medicaid (HCFA-Pub. 23-6)

The Regional Office Manual (ROM) is the primary vehicle for policy and other program issuances to the Regional Offices. It contains policy information explaining and clarifving material in the

regulations. Following are transmittals issued from January through September 1980.

Part 1 — General (HCFA-Pub. 23-1)—None

Part 2 — Medicare (HCFA-Pub. 23-2)

234 —§1000-1002, introduces criteria, statistical standards and procedures for evaluating Part A contractor performance. (1/23/80)

235 —§1001.4 (Cont.)—This page is being issued as it was inadvertently omitted from revision 234. (2/26/80)

236 —§3510, Bills Received and Returned Report.—This is a new computer generated report that replaces the existing evaluation report. (4/2/80)

237 —This revision of the Part A Quality Assurance Appendix contains instructions for the HHA Cost Report Eval. Pgm. (HHA-CREP) (5/12/80)

238 —Sec. 2206, Procedures for Monitoring and Identifying States With Excessive Premium Arrearages. (7/29/80)

239 —This revision to the Part A Quality Assurance App. contains revised instructions to the Hosp. Cost Report Eval. Program (Hosp-CREP). (9/9/80)

240 —S4280. Violation of Assignment Agreement (9/8/80)

241 —Sec. 1008, How the Cost Report Evaluation Program Relates to the ACER. (9/18/80)

242 —Sec. 2215, Evaluation of Individual State Buy-In Operations, explains the technique to be employed by the Regional Offices for the evaluation of States' buy-in operations. (9/24/80)

243 —This transmittal issues new policy for furnishing title XVIII claims information to title XIX State agencies. In view of the extensive changes made, no brackets have been used. (9/26/80)

Part 3 — Program Integrity (HCFA-Pub. 23-3)

10 —Sec. 4070.C.3, External Peer Review—Controls to Ensure Timeliness of Determinations Concerning Overutilization of Part B Medicare Services advises the

regional offices of controls to be utilized by carriers on all referrals made for external peer review. (2/13/80)

Part 4 — Standards and Certification (HCFA-Pub. 23-4)

1 —This new manual represents the culmination of a major part of HSQB's efforts, in conjunction with Regional Offices and other Central Office components, to review, consolidate, and revise where appropriate, all standards and certification policies and procedures. (2/13/80)

2 —Divider Tabs for Regional Office Manual, Standards and Certification (3 sets-3-tabl positions). (7/3/80)

Part 5 — Professional Standards Review (HCFA-Pub. 23-5)—NONE

Part 6 — Medicaid (HCFA-Pub. 23-6)

41 —Chap. 10, 5645—State Medicaid Cost Report Forms on Long-Term Care Reimbursement Programs. (4/15/80)

1 —This transmittal contains the instructions for regional office staff to use conducting quality control reviews of State Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) program administration. (6/23/80)

REGIONAL LETTER SERIES (HCFA-Pub. 16)

The Regional Letter (RL) Series convey material which has limited or no retention value in the following HCFA areas: (1) General, (2) Medicare, (3) Program Integrity, (4) Standards and Certification, (5) Professional Standards Review, (6) Medicaid. The RL Series includes informational and instructional material such as copies of reports and one-time requests to investigate certain areas. A numeric listing of Medicaid RLs issued from January through September 1980 follows:

RL-80-1 —Abortion Reporting—ACTION (1/15/80)

RL-80-2 —Utilization Control: Instructions for Reviewing States' Quarterly Showings Under 1903(g) for the Quarter Ending 12-31-79.

RL-80-3 —Redefinition of Development Disabilities. (1/28/80)

RL-80-4 —Utilization Control (UC) Validation Survey for the Quarter Ending December 31, 1979—Action (2/4/80)

RL-80-5 —State Use of SDX in Medical Eligibility Determinations —ACTION. (2/4/80)

RL-80-6 —Updating the Medicaid Services State by State Chart. (2/11/80)

RL-80-7 —HCFA Corrective Action Strategy. (3/20/80)

RL-80-8 —Procedures for Ordering Medicaid Quality Control Forms (3/20/80)

RL-80-9 —Improvement of Medicaid State Agency Personnel Administration—Application of Federal Merit System Requirements (3/25/80)

RL-80-10 —Selected Changes in State Medicaid Programs (3/25/80)

RL-80-11 —Suspension of Prior Year Medicaid Claims as a Result of the FY 1980 Appropriations Bill (3/28/80)

RL-80-12 —Completion Dates for the Medicaid Quality Control (MQC) Positive & Negative Reviews for the April-September 1979 Review Period (4/3/80)

RL-80-13 —Federal Reporting Module—INFORMATION (4/14/80)

RL-80-14 —Draft Format for Annual State Evaluation Report (ASER) for FY 1980—ACTION (4/15/80)

RL-80-15 —Supplemental Sample of Paid Claims Matched Against Eligibility File—ACTION (4/22/80)

RL-80-16 —Revisions to Medicaid Quality Control (MQC) Statistical Reporting Tables (4/25/80)

RL-80-17 —Abortion Reporting (4/28/80)

RL-80-18 —Medicaid Quality Control Data Submission Schedule for the April-September 1979 Reporting Period (5/1/80)

RL-80-19 —Right to Financial Privacy Act of 1978 & Its Impact on Federal Medicaid Quality Control Re-reviews—INFORMATION (5/13/80)

RL-80-20 —Clarification to Error Rate Calculation (5/13/80)

RL-80-21 —Utilization Control: Instructions for Reviewing States' Quarterly Showings Under Section 1903(g) for the Quarter Ending March 31, 1980 (5/14/80)

RL-80-22 —Utilization Control (UC) Validation Survey for the Quarter Ending March 31, 1980 (5/20/80)

RL-80-23 —State Plan Amendment Status Report, December 31, 1979 (6/3/80)

RL-80-24 —Questions and Answers from Meetings of Regional Medicaid Quality Control Chiefs, October 31-November 1, 1979 (6/9/80)

RL-80-25 —Training Sessions on Completion of the Revised Form HCFA-25 "State Agency Budget Forecast and Quarterly Grant Requirements" (6/26/80)

RL-80-26 —Exemplary or Best Practices for Medicaid Management—ACTION (6/30/80)

RL-80-27 —Instructions for Implementing Medicaid Quality Control (MQC) Monthly *Negative Case Action Report* —ACTION (7/8/80)

RL-80-28 —Abortion Reporting—ACTION (7/31/80)

RL-80-29 —Regional Office Decision Package on the Revised Form HCFA-25 "State Agency Budget Forecast and Quarterly Grant Requirements"—INFORMATION (8/5/80)

RL-80-30 —Completion Dates for the Medicaid Quality Control (MQC) Positive and Negative Reviews for the October-March 1980 Review Period—ACTION (8/6/80)

RL-80-31 —Preparation for the Onset of EPSDT QC Reviews (8/26/80)

RL-80-32 —State Plan Amendment Status Report, March 31, 1980 (9/11/80)

RL-80-33 —Medicaid Quality Control (MQC) Subsample Size (9/11/80)

RL-80-34 —Utilization Control: Instructions for Reviewing State's Quarterly Showings Under Section 1903(g) for the Quarters Ending June 30 and September 30, 1980—ACTION (9/18/80)

RL-80-35 —Providing Medicare Claims Information to Title XIX Agencies (9/26/80)

RL-80-36 —Senator Durenberger's Request for Information on State Medicaid Funding of Psycho-Social Rehabilitation Services (9/30/80)

MEDICARE

PART A. INTERMEDIARY MANUAL AND LETTERS

The Part A Intermediary Manual and Letters encompass the policies and procedures which govern intermediaries in carrying out their administrative and financial responsibilities for claims review, bill payment, applying utilization safeguards, and other responsibilities in connection with administration of the Medicare Program. Copies of the manual and letters may be requested in all Health Care Financing Administration Regional Offices.

Organization of the Part A Intermediary Manual:

Part 1—Fiscal Administration

Part 2—Audits—Reimbursement—Program Administration

Part 3—Claims Process

MEDICARE CARRIERS MANUAL AND LETTERS

The Medicare Carriers Manual and Letters encompass the policies and procedures which govern carriers in performing their administrative and financial responsibilities for claims review, bill payment, applying utilization safeguards and other responsibilities in connection with Administration of the Medicare Program. Copies of the manual and letters may be requested in all Health Care Financing Administration Regional Offices.

Organization of the Medicare Carriers Manual:

Part I—Fiscal Administration

Part 2—Program Administration

Part 3—Claims Process

CARRIER QUALITY ASSURANCE PROGRAM HANDBOOK AND BULLETINS

The CQ Handbook contains carrier processing and systems instructions for evaluating the quality of Part B claims adjudication. The Bulletins serve a temporary informational purpose, containing items of interest which will be manualized shortly.

Organization of the Carrier Quality Assurance Program Handbook:

HOSPITAL MANUAL

The Hospital Manual contains the policies and procedures applicable to the delivery of hospital services, including claims processing instructions, billing procedures, coverage requirements, and related matters governing hospital performance under the Medicare program. Copies of the manual are available for inspection and copying in all Health Care Financing Administration Regional Offices.

Organization:

MEDICARE FOREIGN HOSPITAL SUPPLEMENT

Organization:

CHRISTIAN SCIENCE SANATORIUM HOSPITAL MANUAL SUPPLEMENT

Organization:

SKILLED NURSING FACILITY MANUAL

The Skilled Nursing Facility Manual contains the policies and procedures applicable to the delivery of skilled nursing facility services, including claims processing instructions, billing procedures, coverage requirements and related matters governing skilled nursing facility performance under the Medicare program. Copies of the manual are available for inspection and copying in all Health Care Financing Administration Regional Offices.

Organization:

HOME HEALTH AGENCY MANUAL

The Home Health Agency Manual contains the policies and procedures applicable to the delivery of home health services including claims processing instructions, billing procedures, coverage requirements and related matters governing home health agency performance under the Medicare program. Copies are available for inspection or copying in all Health Care Financing Administration Regional Offices.

Organization:

OUTPATIENT PHYSICAL THERAPY PROVIDER MANUAL

The Outpatient Physical Therapy Provider Manual contains the policies and procedures applicable to the delivery of physical therapy services including claims processing instructions, billing procedures, coverage requirements and related matters governing out-patient physical therapy providers performance under the Medicare program. Copies are available for copying and inspection in all Health Care Financing Administration Regional Offices.

Organization:

GROUP PRACTICE PREPAYMENT PLAN MANUAL AND LETTERS

The Group Practice Prepayment Plan Manual and Letters contain policies and procedures governing the claims processing and billing functions of group practice prepayment plans providing services to Medicare beneficaries under arrangements with the Administration. Copies of the manual and letters are available for inspection and copying in all Health Care Financing Administration Regional Offices.

Organization of the Group Practice Prepayment Plan Manual:

STATE BUY-IN HANDBOOK AND STATE BUY-IN LETTERS

The State Buy-In Handbook and State Buy-In Letters contain policies and procedures governing States having agreements with

the Administration which the States must follow in enrolling and paying premiums for Medicare beneficiaries who are eligible under title XVI or XIX for State assistance in meeting their medical insurance premium liability under Medicare. Copies are available for inspection and copying in all Health Care Financing Administration Regional Offices.

Organization of the State Buy-in Handbook:

DEFICIENCY REPORTS ON PROVIDER SURVEYS (HCFA-2567)

Deficiency Reports on Provider Surveys are summaries of the specific findings of noncompliance with Medicare conditions of participation identified in the periodic surveys of each participating provider of service, e.g., hospital, skilled nursing facility and home health agency. Copies may be requested in all Health Care Financing Administration Regional Offices.

ANNUAL CONTRACTOR EVALUATION REPORTS

Annual Contractor Evaluation Reports are prepared by Regional Offices based on annual reviews of each contractor. They summarize the effectiveness of each contractor's performance under the specific terms of its agreement with the Secretary. Copies may be requested in all Health Care Financing Administration Regional Offices.

PROGRAM VALIDATION STUDIES

Program Validation Studies are periodically issued summaries of the findings of onsite validation teams, who are responsible for reviewing selected aspects of the HCFA program functions of providers of services, e.g., hospitals, skilled nursing facilities and home health agencies, as well as intermediaries and carriers, primarily to determine the effectiveness of current policies and procedures in the program areas being investigated. Copies may be requested in all Health Care Financing Administration Regional Offices.

PREVAILING CHARGE SCREENS

Prevailing charge screens represent the highest allowable charges Medicare will recognize in various geographical areas for determining medical insurance benefits payable for physician and supplier services covered by the program. The prevailing charge

screens are updated in July of each year and show for each covered service or supply the prevailing charge applicable for that service or supply in specified geographical areas. Copies can be requested in all Health Care Financing Administration Regional Offices.

PROVIDER COST REPORTS

Provider Cost Reports are submitted, on an accounting year basis, by each participating provider of services. These reports summarize all relevant costs by the provider and are the basis for determination of reimbursable costs. Copies may be requested in writing from the provider's fiscal intermediary, or from the Health Care Financing Administration Regional Offices.

PROVIDER REIMBURSEMENT MANUAL

The Provider Reimbursement Manual describes the various methods used and the expenses which are allowable in computing reasonable cost reimbursement for providers of services, e.g., hospitals, skilled nursing facilities and home health agencies, clinics, rehabilitation agencies or public health agencies. Copies are available for inspection and copying at all Health Care Financing Administration Regional Offices.

Organization:

STATE OPERATIONS MANUAL (HCFA-PUB.7)

The State Operations Manual is the State Agencies' basic guide to HCFA policies and procedures. Copies of the manual are available for inspection and copying in all Health Care Financing Administration Regional Offices.

RURAL HEALTH CLINIC MANUAL (HCFA-PUB. 27)

The Rural Health Clinic Manual contains policies and procedures applicable to the delivery of rural health clinic services, including claims, billing instructions, coverage requirements and related materials governing rural health clinics' performance under the Medicare program. Copies of the manual are available for inspection and copying in all Health Care Financing Administration regional offices.

RENAL DIALYSIS FACILITY MANUAL (HCFA-PUB. 29)

The Renal Dialysis Facility Manual contains policies and procedures applicable to the operation of nonhospital renal dialysis facilities under the Medicare program. Copies of the manual are available for inspection and copying in all Health Care Financing Administration Regional Offices.

GROUP PREMIUM PAYMENT HANDBOOK AND GROUP PREMIUM LETTERS

The Group Premium Payment Handbook and Group Premium Letters contain the policies and procedures governing the group payment of Medicare insurance premiums and are issued to various groups and organizations which pay the premiums for their members for voluntary hospital insurance and supplementary medical insurance under Medicare. Copies are available for inspection and copying at all Health Care Financing Administration Regional Offices.

PROGRAM CIRCULARS

Health Insurance program circulars are issued by HCFA as well as by the various regional offices for two purposes; 1) to alert personnel to new program developments prior to the issuance of new manual sections: and 2) to clarify existing policies and procedures which

have been issued in manual form. Copies of the circulars are maintained in Health Care Financing Administration Regional Offices and are available for inspection and copying there.

PART B MODEL SYSTEMS

This is a software computer system available to carriers for processing Part B claims. The system contains the necessary programming for carriers to review bill payments applying utilization safeguards and other responsibilities assigned to them. Copies may be requested in all Health Care Financing Administration Regional Offices.

DIRECTORY OF MEDICAL FACILITIES

The Directory of Medical Facilities is a listing of providers (participating hospitals, emergency hospitals and those which can continue a benefit period (spell of illness); participating skilled nursing facilities and home health agencies). It also lists the intermediaries which process provider claims.

MAGNETIC TAPE SPECIFICATIONS HANDBOOK

The Magnetic Tape Specifications Handbook supplies intermediaries with the standards and criteria they must use in submitting bills on magnetic tape rather than on hard copy.

CLAIMS MANUAL

The Claims Manual is a Social Security Administration publication which contains the policies and instructions for SSA. However, included in the Claims Manual, Parts 10 and 11, are instructions concerning the responsibilities of the components administering Medicare: entitlement requirements for Part A-Hospital Insurance and Part B-Supplementary Medical Insurance benefits; instructions and policies to resolve entitlement problems; monthly premium amounts and premium collection policies and procedures; termination of entitlement; policies and procedures for the filing of claims, recovering overpayments, making underpayments, waiver of liability provisions, Medicare appeals, and in general, policies dealing with definitions: e.g., hospital services, physician, benefit period, medical necessity, as well as identifying services which by law are excluded from coverage. Copies of these sections of the Claims Manual are maintained in all Health Care Financing Administration Regional Offices and are available for inspection and copying there.

All SSA program instructions, including the Claims Manual are currently being converted into a unified body of instructions, the Program Operations Manual System (POMS).

PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS TRANSMITTALS

The Professional Standards Review Organizations (PSRO) transmittals contain administrative, procedural, and policy instructions for use in administering the PSRO program. A numeric listing of these PSRO transmittals issued from January through September 1980 follows:

88A —Model Memorandum of Understanding Between End-Stage Renal Disease Medical Review Boards and Professional Standards Review Organizations (9/19/80)

92 —Processing of PSRO Sanction Reports Submitted by the PSRO Pursuant to Sections 1157 and 1160(b) of the Social Security Act (4/21/80)

93 —Full Designation Criteria (4/25/80)

94 —Waiver of Liability (6/24/80)

95 —National PSRO Program Priorities for Objective Setting (7/7/80)

96 —Current PSRO Program Policy and Activities Relating to Concurrent Review Criteria (7/11/80)

97 —Long Term Care (LTC) Review Objective Setting (8/18/80)

98 —Role of PSROs in Review of Office of Research, Demonstrations, and Statistics (ORDS) Demonstration Projects (8/18/80)

99 —PSRO Responses to Audit Findings—ACTION (9/29/80)

TECHNICAL ASSISTANCE DOCUMENTS (PSRO)

The technical assistance documents provide assistance in the implementation of the various administrative and technical aspects of the PSRO operation.

19 —Analysis of PSRO Review Costs (1/31/80)

20 —Assistance in the Development of a System for the Evaluation of the Executive and Medical Director Positions (3/13/80)

21 —Technical Assistance Document (TAD) for State Medicaid Agency Monitoring of PSROs (4/3/80)

22 —Technical Assistance Document, "Approaches to the Review of Respiratory Therapy Services" (7/28/80)

23 —PSRO Data Processing Test Package (Revised) (8/29/80)

GENERAL MEMORANDA (PSRO)

General memoranda are used to disseminate information of a general advisory nature to PSROs about aspects of program administration.

01-80 —Conducting Multidisciplinary and Interdisciplinary Medical Care Evaluation Studies (2/11/80)

02-80 —PSRO Review of Routine Hospital Admission Tests (3/3/80)

03-80 —Summary of the PSRO LTC Review Conference (6/10/80)

PROFESSIONAL STANDARDS REVIEW REGIONAL LETTERS (HCFA-Pub. 55)

80-1 —Audit Resolution Procedures (9/29/80)

Part VI, Legislation

The following legislation affecting HCFA programs were enacted during the period January 1, 1980 through September 30, 1980:

Adoption Assistance and Child Welfare Act of 1980

On April 23, 1980, the Conference Report on H.R. 3434, the "Adoption Assistance and Child Welfare Act of 1980," was filed by the House and Senate Conferees. This bill contains several provisions that affect the Medicare and Medicaid programs. On June 13, both the House and the Senate adopted the Conference Report in voice votes. The President signed the bill into law on Tuesday, June 17, 1980. It is now Public Law 96-272.

The provisions of P.L. 96-272 that relate to the Medicare and Medicaid programs are the following:

- Establishment of a federally matched adoption assistance program under a new Title IV-E of the Social Security Act.
- Broadening of eligibility for foster care maintenance payments under the Social Security Act.
- Limitation on period for State filing of claims under the Social Security Act.
- Exchange of information on terminated or suspended providers under Medicare and Medicaid.
- Continuation of Medicaid eligibility for certain recipients of VA pensions.

Social Security Disability Amendments of 1980

On June 9, 1980, the President signed into law H.R. 3236, (Public Law 96-265) the "Social Security Disability Amendments of 1980." This law contains a series of provisions which would affect the Medicare and Medicaid programs.

The Provisions of P.L. 96-265 which relate to the Medicare and Medicaid programs focus on three major areas:

- The establishment of a voluntary certification program for Medicare supplemental health insurance policies.
- Amendments related to disability benefits under Medicare and Medicaid.
- Expanded authority for demonstration projects.

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THIRD CLASS